A CLINICAL STUDY ON

VELLAI NOI

(LEUCORRHOEA)

WITH THE EVALUATION OF SIDDHA DRUG

AGHIL KATTAI CHOORANAM

The dissertation submitted by

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CERTIFICATE

This is to certify that the dissertation entitled "**A CLINICAL STUDY ON VELLAI NOI "** is a bonafide work done by **Dr. X.HELEN SATHIYA.**, Government Siddha Medical College, Chennai – 600 106 in partial fulfillment of the University rules and regulations for award of **SIDDHA MARUTHUVA PERARIGNAR** under my guidance and supervision during the academic year 2014 – 2017.

Name & Signature of the Guide

Name & Signature of the HOD

Name & Signature of the Principal

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CONTENTS

INTRODUCTION

Siddha Medical Science is very ancient in origin, as old as the earliest civilisation. The exact time of its existence cannot be ascertained as it is also categorically stated that it was before the spitting out come of sand from the stone.

"கல்தோன்றி மண் தோன்றாக் காலத்தே

வாளோடு முன்தோன்றிய மூத்தகுடி".

The Siddha medicine has regained its world worthy status with the new enterprising uplift by Tamil enthusiasts. My earnest endeavour is to narrate a brief account of the greatness of Siddha medicine, from the ancient Tamil Literature. The great Siddha medicine is illustrious about the spiritual wisdom, scientific knowledge, anatomical structures, religion and philosophy, astrology, Breathing exercise, medical science and heating therapy.(1)

Siddha science considers nature and man as essentially one. Man is a part and parcel of the universal nature. Nature functions well in the human system. A man who identifies himself with nature is sure to know everything of nature. One who knows himself knows the universe as well. Saint Thiruvalluvar, in his immortal Tamil Classic Thirukkural says that those who have well understood the five senses of taste, sight, touch, sound and smell may be deemed to have comprehended the nature of the world.

This holds well in case of good physician too. Abuse of nature's law upsets the human system and diseases occur.

According to Siddha medical science, the universe originally consisted of atoms which contributed to the five basic elements viz, Earth, Water, Fire, Air and Ether, which corresponded to the five senses of the human body and they were the fundamentals of all the corporeal things in the world. A close relationship is found to exist between the external world and the internal system of man. Siddhars maintain that the structure of the human body is a miniature of the world in them itself. (2) In the modern world, treatment is done by herbs takes an important position. In the early periods, herbal medicine was widely used in India. (3)

In Siddha, Pathological Leucorrhoea is compared with *Vellai noi. Vellai noi* and its treatment aspects have been mentioned in various Siddha classical texts. As per saint Yugi, *Vellai noi* is one among the 21 types of Yoni Rogam which can be correlated with specific leucorrhoea (*Candida albicans, Gardnerella vaginalis* etc) in Modern science.(4)

The word "Leucorrhoea" is a Greek word made up of two words i.e (Lu-ko-re'ah) Leukos means White and rhoea means flow. It is one of the most annoying yet common gynaecological complaints. (5)

Leucorrhoea is a condition of persistent and excessive vaginal discharge. It is a common complaint particularly among women in our country. Women may complain of a clear white discharge or mucous discharge other prior to menses or at mid cycle and the discharge may originate from vagina, ovaries, fallopian tubes or most commonly the cervix.

"The development of nation lies in the empowerment of women"

Reproductive health is closely associated with culture of a country as it is well appreciated from the poetic version of Saint Yugi i.e., excessive lust will be the precipitating factor for *Vellai noi.* *(6)*

Vellai noi affects the women commonly and frequently women in any reproductive age group & even young girls are commonly affected by *Vellai noi* .The incidence of *Vellai noi* is found in woman irrespective of their socioeconomic status. Vaginal infection is more common in women of childbearing age & in older women. The factors like increasing age, illiteracy, low socioeconomic status, high parity, induced abortion are all contributing factors for occurrence of vaginal discharge. (7)

Gardnerella vaginalis is considered responsible for bacterial vaginosis, a mild but common condition characterised by foul smelling discharge and the presence of 'clue cells', which are vaginal epithelial cells with their surface studded with numerous small bacteria.

Moniliasis is caused by *candida albicans*, gram positive yeast - like fungus. The patient complains of curdy white vaginal discharge with intense vulvovaginal pruritus. (8)

Siddha formulations not only treat this disease but also strengthen the Uterus, vagina without any undesirable effects. We are receiving more number of *Vellai noi* cases in our hospital which is the driving force behind me to select this disease for my dissertation study.

As preparation of the trial drug ***AGHIL KATTAI CHOORANAM*** is efficacious & easily available, I have chosen ***AGHIL KATTAI CHOORANAM*** as my drug of choice for the treatment of *Vellai noi.* So there is a need to evaluate the safety and therapeutic efficacy of this classical Siddha formulation "*AGHIL KATTAI CHOORANAM*" for scientific validation.

AIM AND OBJECTIVES

AIM:

The purpose of this study is to evaluate the safety and efficacy of Siddha herbal formulation

"*AGHIL KATTAI CHOORANAM* '' in the treatment of Vellai *noi.*

OBJECTIVES:

- Collection of various Siddha literatures of the study.
- Herbal identification and authentication of the trial drug.
- To prepare the trial drug "*AGHIL KATTAI CHOORANAM*" as per Standard operating procedure drug preparation.
- To study the evaluation of Siddha trial drug "*AGHIL KATTAI CHOORANAM*" for *Vellai noi.*
- To evaluate the Biochemical, Anti-microbial & Physio-chemical analysis of the trial drug.
- To evaluate the safety profile like Acute toxicity , Sub acute toxicity of the trial drug in animal models as per OECD guidelines
- To evaluate the pharmacological analysis of Anti-bacterial, Anti-fungal activity for the trial drug by using culture method.
- To correlate the Siddha aspects of *Vellai noi* to specific pathogenic Leucorrhoea of modern medicine with respect to etiology, pathology, and clinical features.
- To gather the Siddha diagnostic parameters by *Mukutram, Udal thathukkal, Uyir thathukkal* and *En vakai thervugal.*
- To use modern parameters to confirm the disease.
- To make a clinical observation about the disease in relation of age, sex, occupation, socio-economic status.
- The haematological analysis, urine analysis, vaginal smear, ultra sonogram studies will be done to all patients.
- All patients are subjected to thorough investigation before and after treatment.
- To find out the statistical analysis and efficacy of the drug through clinical study.

VELLAI NOI

VERUPEYARGAL (SYNONYMS)

Vettai noi, Piramegam, Piramiyam, Ozhukku noi.

Vellai noi is one among *Neerinai arukkal noi*.

"நீரிரு வினைக்குணத்தை நீயறி விரித்துச் சொல்வாம்
நீரினைப் பெருக்க லொன்று நீரினை யருக்க லொன்று
நீரிழிவுடனே கொல்லும் நீர்க்கட்டு வினைக ளொன்று."

The classifications are as follows:

- *Kalladaippu*
- *Neer surukku*
- *Neer kattu*
- *Chottu neer and*
- *Vellai noi*[9]

IYAL (DEFINITION):

Leucorrhoea or white discharge is mucus like fluid that comes from the inner mucosal layer of Uterus or vaginal cervix. [10]

NOI VARUM VAZHI-AETIOLOGY:

ACCORDING TO YUGI MUNI

இயம்பவே எளியோரை யிகழ்ச்சி சொல்லல்
ஏற்றமாம் பெரியோரை யேவல் கொள்ளல்
புயம்பவே பொன்றனையே சோரஞ் செய்தல்
பொருள்தனையபகரித்தல்பெருமை சொல்லல்
நயம்பவே நம்பினர்க்கு நஷ்டஞ் செய்தல்
நாட்டமா யெந்நேரம் பெண்மோ கித்தல்
பயம்பவே பயந்து வந்த பேரைக் காட்டல்
பழித்தபேர் பிரமியத்திற் படும் பாடாமே

பாடாகப் பெண் போகமி கவிரும்பிப்
பயின்றிட்டுப் பட்டினியே மிகவிருத்தல்
தாடாகத் தான் பாதத்தில் சூடு தாங்கல்
சரசமாய் காரத்தை மிகப் பொசித்தல்
ஊடாக வுப்புரைப்புத் துவர்ப்பு மிஞ்சல்
உக்கிரமாம் பலபலவாம் விசேஷம் செய்யல்
காடான மனக்கிலே சங்கா ரமான
கைத்தலோடு மிருக்கலி துகா ணுக்கானே" (11)

- யூகி வைத்திய சிந்தாமணி

1. Ridiculing the downtrodden
2. Commanding elders
3. Filching gold
4. Pilfering other's things
5. Self-praising
6. Bringing loss to others
7. Always having the thought of sexual indulgence
8. Severe Starvation
9. Prolonged walking in the sunlight that leads to enormous production of heat in the soles
10. Increased intake of spicy food, salty food, astringents and bitter tasty foods

II. ACCORDING TO AGASTHIYAR GUNAVAGADAM

"கேளடா பிரமேக உற்பத்தி தன்னை
கெணிதமுடன்சொல்லுகின்றேன் நன்றாய்க் கேளு
நாளடா ஸ்த்ரீபோகம் அதிகரித்தாலும்
நன்மையுடன் மோகமுடன் பட்டினி யாலும்
வாளடா ஸ்தம்பனங்கள் செய்வ தாலும்
வளமான காரமுடன் துவர்ப்பு உப்பு
பாழடா அதிகமாய் புசிப்ப தாலே
பாங்கான பிரமேகந் தோணும் பாரே" (12)

-அகத்தியர் குணவாகடம்

1. Excessive sexual indulgence
2. Lustfulness with starvation
3. Restraining the ejaculation of semen during sexual intercourse
4. High intake of, hot, salty and sour foods.

III ACCORDING TO THIRUMOOLAR KARUKKADAI VAITHIYAM

"அன்னம் பிறந்தது அனைத்து விதையிலும்
மன்னிய வெட்டை மகாசீதம் இரண்டினால்
பன்னி அறிந்திதைப் பார்ப்பார் பெரியோர்கள்
கன்னி மயக்கத்தால் கண்டிடும் மேகமே"

“மேகம் பிறந்த விதந்சொன்னா எந்நந்தி
ஆகம் இளந்தைப் பருவத்தில் மோகித்துப்
போகந் தினஞ்செய்யில் புகழ் மந்தத்தே கூடில்
வாகப் பசியால் வழங்கும் சையோகமே"

“சையோகம் செய்யத் தனித்த சுழியோடும்
ஐயா அமிர்தம் அடங்கிக் கனலேறும்
மெய்யாக விந்து விழப் புண்ணாகும்
மையான மேகம் வளருங் கிரந்தியே" (13)

-திருமூலர் கருக்கடை வைத்தியம்

Sexual act in the adolescent age should be avoided during digestive disturbances and improper practice of kundalini yoga.

IV. ACCORDING TO AGASTHIYAR VAIDDHIYA KAAVIYAM 1500

"மேகங்கள் பிறந்து நின்ற விதங்களை விளம்பக்கேளு
ஆகங்கள் இகழ்ந்தபோது அப்பனே தினமும் சென்று
போகங்கள்செய்யும்போதும்புகழ்மந்தம்கூட்டும் போதும்
பாகங்கள் பசியனூடும் பருகுஞ் சையோகந்தானே
சையோகஞ் செய்யும்போதும் தனிநின்ற சுழியேயோடு
மையவோ அமுர்தந்தன்னை அடக்கியே அனல்தான் கொள்ளும்
மெய்யடா விந்துகாணில் விழவிழப் புண்ணுந்தானு
மையடா மேகத்தாலே வளர்ந்தது கிரந்திபாரே" (14)

-அகத்தியர் வைத்தியம் 1500

Insulting or reticulating the sacred books, excessive sexual act, having sex during indigestion & hungry and suppressing the ejaculation of semen during sexual act cause Meganoi.

V. According to **T.V.SAMBASIVAM PILLAI** the chief causes of *Vellai noi* is

- Veneral disorder
- Improper dietary habits
- Intemperate habits
- Conceptional defects
- Prostitution [15]

VI. According to **Prof.Dr.Venugopal** in his text Magalir Maruthuvam

1. Due to physiological factors
2. Altered sexual indulgence. [16]

MURKURIGUNANGAL (SIGNS):

- Past history of having intercourse with the infected persons
- Itching in the external reproductive organ
- Burning sensation in the urethra
- The nature of the urine is present as pus along with urine [17]

NOI VAGAIKAL - (CLASSIFICATION):

Vellai noi is classified by various types of authors; some of the types are below.

Yugimuni classified penkuri roga padalam into 20 types. They are as follows

- Vaatha Yoni Rogam
- Pitha Yoni Rogam
- Kaba Yoni Rogam
- Kuruthi Yoni Rogam
- Kuruthi seezh Yoni Rogam

- Vali Yoni Rogam
- Kothippu Yoni Rogam
- Soolai Yoni Rogam
- Sutka Yoni Rogam
- Kozhai Yoni Rogam
- Sivappu Yoni Rogam
- Vadi Yoni Rogam
- Maga Yoni Rogam
- Nabojaga Yoni Rogam
- Adhisarana Yoni Rogam
- Thoolidha Yoni Rogam
- Poopukaala Yoni Rogam
- Kirumi Yoni Rogam
- Thamaraikkai Yoni Rogam
- Vibareetha punaroni Rogam [18]

In Theran karisal aspect

"உரைத்திட்டேன் பிரமியென்ற நோயைத் தானே
உத்தமனே இருபத் தொன் றாங் கண்டாயே"

"எழுத்தவே பிரமியத்தின் பெயரைக் கேளாய்
வாதத்தின் பிரமியமாம் பித்தப் பிரமியம்
திழுத்தவே சிலேட்மத்தின் பிரமி யந்தான்
சீரான வாதபித்தப் பிரமிய மாகும்
நழுத்தவே பித்தசிலேட்மப் பிரமி யந்தான்
நலந்தொந்தப் பிரமியமாங் கட்டிப் பிரமியம்
தழுத்தவே சலப்பிரமியந் தந்திப் பிரமியந்
தனித்ததோ ரிரத்தப்பிர மியந்தா னென்றே"

"தானென்ற சீப்பிரமிய மொழுக்குப் பிரமியந்
தனியரித்திராப் பிரமியமாங் கிரிச்சரப் பிரமியங்
கானென்ற கரப்பனமாம் பிரமியத் தோடு
கல்விளையும் பிரமியமாந் தந்துப் பிரமியம்

நேனென்ற நீச்சுப்பி ரமியம் மலினப் பிரமியந்
நேரான மதுப்பிரமியம் விரணப்பிரமியம்
ஏனென்ற பிரமியந்தா னிருபத் தொன்று
இதனுடைய உற்பத்தி யியம்பக் கேளே” (19)

-தேரன் காசிசல்

1. Azhal Vellai
2. Iyya Vellai
3. Vali azhal Vellai
4. Azhal iyya Vellai
5. Mukkuttra Vellai
6. Katti vellai
7. Neer vellai
8. Thanthi Vellai
9. Seezh Vellai
10. Ozhukku Vellai
11. Manjal Vellai
12. Neerkattu Vellai
13. Karappan Vellai
14. Kal Vellai
15. Thandhu Vellai
16. Neechu Vellai
17. Vali vellai
18. Thaen Vellai
19. Pun Vellai
20. Rattha Vellai
21. Vatha Vellai

According to the text, Roga nirnaya saram,

1. Vaadha piramegam
2. Pitha piramegam
3. Sileshma piramegam
4. Arithira piramegam
5. Thanthi piramegam
6. Seezh piramegam

7. Ratha piramegam
8. Jala piramegam
9. Ozhukku piramegam
10. Katti piramegam
11. Rana piramegam
12. Kirichara piramegam
13. Neechu piramegam
14. Karappan piramegam
15. Malina piramegam
16. Mathu piramegam
17. Thanthu piramegam
18. Kallu piramegam
19. Pitha silaethma piramegam
20. Vaathapitha piramegam
21. Thontha piramegam [20]

KURIKUNANGAL (SYMPTOMS)

According to Yugimuni

"பார்க்கவே சேத்துமத்தின் ரணங்கள் காணும்
பாழான சீதளம் மிகுத்துக் காட்டும்
ஏர்க்கவே சீதளமுந் தினவுங் காணும்
எழிலான வேதனையு மிகப்பு டைக்கும்
ஆர்க்கவே வல்குலிலே வெளுமை காணும்
அப்பனே நீர்க்கசிவு மதிக மாகும்
தீர்க்கவே யூகிமுனி சிகிச்சா சாரம்
தெளிவாகப் பாடிவைத்தார் திறமி தாமே"

- Ulcerative lesions will be present
- Increased white discharge
- Itching and painful sensation seen in vulva.
- Paleness will be felt in the vulva by palpating it.

"வாறான சையோக மிகுதி யாலும்
வல்குலிலே சோரியது கெட்டு மேதான்
தூறான கிருமிகளு மிகவுண்டாகி
தொடருமேநமைச்சலுடன் விருப்பங் காணும்

நாறான நாற்றமுட னுதிரந் தோன்றும்
நவிலவே முடியாது களையின் வேகம்
காறான யூகிமுனி சிகிச்சா சாரம்
கருதினார் லேகத்து மாண்ப ருக்கே" (21)

- Excessive sexual indulgence
- Itching in the external genetalia due to infection
- Painful and foul smelled vaginal discharge will be present.

According to Theran karisal

"கடுத்துமே சீப்போல வெள்ளை காணுங்
கட்டுமே அரையாப்பு பவுத்தி ரந்தான்
நடுத்துமே நாபியெலாம் விரண மாகும்
நற்சந்துக் கணுக்காலிற் குடைச்ச லுண்டாம்
அடுத்துமே யடிக்கடிக்கு நீரி றங்கும்
அதிகமாய்க் குளிரோடு சுரமு முண்டா
மடுத்துமே வருத்தமாய் மயக்க மாகும்
வடிவமெலா நொந்திடுஞ்சீப் பிரமிய மாமே"

- Lymphadenitis, fistula will be present.
- Ulceration occurs in umbilical area.
- Pain will be present in all major and minor joints.
- Increased frequency of urination.
- Fever, Rigor, tumors in the genitals, giddiness will be present.

"அரித்திரம்போ னீரிறங்கு மாண்மை குன்று
மருக்கியே மிகக்கடுத்து நீர்தான் வீழும்
நெரித்திரம்போ னீர்தனையே கட்டிக் கொள்ளும்
நிரசியம்போற் சரீரத்தி லுறக்க மில்லை

தரித்திரம்போ லன்னத்தைப் பொசிக் கொட்டாது
சஞ்சலமாய் மனதுதான் றரிக்கொட் டாது
விரித்திரம்போ லுடம்பெல்லா முளைச்ச லுண்டாம்
விகிழுத்திரக் கிரிச்சரப் பிரமியந் தானே" (22)

- Painful, yellowish discharge will be present in the urethra.
- Frequent micturition will be present.
- Dysuria will be present.
- Sleeplessness will be present.
- Loss of appetite will be present along with mental disturbances.
- Body pain will be present.

MUKKUTRA IYAL (PATHOLOGY):

Certain extrinsic and intrinsic factors alter the equilibrium of tridosha and produce the disease. *Vellai noi* is mainly due to aggravated pitha humour which is evident from the quote mentioned below,

"பகர்பித்த விந்தையலாது மேகம் வாராது" (23)
-தேரையர்

It denotes that alteration of pitham causes mega diseases. Altered pitham affects abanan and viyanan.

Affected abanan alters the theyu pootham which leads to burning sensation in the urethra, burning micturition, purulent discharge in the urethra, low back pain and constipation.

Affected viyanan alters akaya pootham which leads to loss of appetite, fatigue, pain all over the body, emaciation, altered sleep rhythm and mental tiredness. (24)

PINIYARI MURAIMAI – (DIAGNOSIS):

"Pini means the disease which affects the body". Any interruption of the normal functions of any body part, organ or system.

"Ari means identify". "Muraimai means method of diagnosing"

Piniyari muraimai is the method of diagnosing the disease in affected people. It is based upon the following aspects:

1. Poriyalarithal
2. Pulanaalarithal
3. Vinaathal
4. Envagaithervugal
5. Naadiparitchai

The above principles correspond to the methodology of inspection, palpation and interrogation of modern medicine.

Poriyalarithal:

"Pori"- are the five organs of perception namely,

1. Nose
2. Tongue
3. Eyes
4. Ears and
5. Skin

Pulanarithal:

"Pulan" is the five object of sense namely

1. Smell
2. Taste
3. Vision
4. Hearing
5. Touch respectively.

Physician's pori and pulan are used as the tools for examining the pori, pulan of the patient.

Vinathal:

It is a procedure interrogating for gathering information about the patients name, age, occupation, nativity, socio economic status, family history, dietary habits, allergic factors, period of suffering from the complaints, history of previous episodes, relevant history of habits and treatment etc…from the patient or from his immediate relatives, if the patient is unable to speak or if the patient is child.

In *Vellai noi* vinathal is very much useful for Piniyarimuraimai, occupation, family history, dietary haits, proper treatment and socio economic status are very important for *Vellai noi.* [(25)]

Enn Vagai Thervugal:

Eight different kinds of tests to be applied or attended by a physician before arriving a correct diagnosis. These are also called Attavitha Paritchai or Attasthanna Parikshai.

Envagai thervugal is considered as physician‘s parameters.

“நாடி பரிசம் நா நிறம் மொழி விழி
மலம் மூத்திரமிவை மருத்துவராயுதம்”

According to Theraiyar

“மெய்க்குறி நிறத்தொனி விழிநாவிருமலம் கைக்குறி” [(26)]

According to Agasthiyar Guna Vagadam:

"தரணியுள்ள வியாதிதன்னை யட்டாங் கத்தால்
தானறிய வேண்டுவது யாதோ வென்னில்
திரணியதோர் நாடிகண்கள் சத்தத் தோடு
தேகத்தினது பரிசம் வருணம் நாக்கு
இரணமல மூத்திரமா மிவைக ளெட்டும்
இதம்படவே தான்பார்த்துக் குறிப்புங் கண்டு
பரணருளால் பெரியோர்கள் பாதம் போற்றிப்
பண்பு தவறாமல் பண்டிதஞ் செய்வீரே"

-அகத்தியர் குணவாகடம்

1. Naadi (Pulse)
2. Sparisam (Palpation)
3. Naa (Tongue examination)
4. Niram (Colour of the body)
5. Mozhi (Speech)
6. Vizhi (Eye Examination)
7. Malam (Motion Examination)
8. Moothiram (Urine examination)

1. Naadi:

Naadi is the vital force and the main diagnostic scale in the Siddha system. Any change in the three doshas is best diagnosed by feeling the naadi. Naadi is responsible for the existence of life and can be felt one inch below the wrist on the radial side by means of palpation with the tips of index, middle and ring finger corresponding to Vatham, Pitham and Kabam. Normally these 3 vital forces exist in the ratio 1:1/2:1/4. Derrangement of this ratio leads to various disease entities. In Vellai noi the following Naadi nadai are seen commonly,

1. Pitham
2. Vatham
3. Vathapitham [27]

In sathaga naadi padal:

"உறுதியுள்ள பித்தமது தோன்றில் வெப்பு
உஷ்ணவாயு வத்திசுர மதிசா ரங்கள்
மறதியுடன் கிறுகிறுப்பு பையித்திய ரோகம்
வளர்சோகை யழலெரிவு காந்தல் கைப்பு
இருதயத்தில் கலக்கமது மறப்பு தாகம்
எழுங்கனவு மேயனைவு மயக்க மூர்ச்சை
சிறிதுபெரும் பாடுரத்தம் பிரமே கங்கள்
சேர்ந்து மிகு பிணபலவுஞ் சிறக்குந் தானே" [28]

-அகத்தியர் குணவாகடம்

Due to derangement of Vatha naadi,

"வாதமெனும் நாடியதுதோன்றில்.....
.....தந்துமேகம்"

2. Sparisam:

The following points are elicited by Sparisam, the temperature of skin (Heat or cold), smoothness, roughness, softness, sweat, dryness, sensation

In *Vellai noi* along with general sparism aspects, it is especially used for per vaginal examination.

3. Naa:

By inspecting the tongue its colour, coating, ulcer, deviation, roughness, silky soft & any abnormality of the tongue is noted.

In *Vellai noi* the tongue will be dry and coated denotes absence of appetite. If anaemia is present the tongue will be pallor.

4. Niram:

It denotes the colour of skin, palm etc. The colour of vaginal discharge expel out represents the type of kuttram.

5. Mozhi:

It constitutes high or low pithched voice, slurring, incoherent speech, nasal speech, hoarseness of voice.

In *Vellai noi* the tone and speech will be in medium mode.

6. Vizhi:

Both motor and sensory disturbances of eye are noted. Burning sensation of eyes, lacrimation, irritation, colour are noted.

In *Vellai noi* burning sensation of eyes is present.

7. Malam (Faeces):

In the examination of Malam, Niram (colour) , Nurai (froth), Erugal (Solid)., Elagal (Semisolid or liquid), quantity (increased or decreased) smell can be noted other examination like diarrhea, presence of blood, mucus, undigested matter in the stools and odour can also be studied.

8. Moothiram: (Urine)

In the examinantion of urine, colour, odour, quantity of urine, the presence of froth, deposits, blood, pus, inorganic sediments, abnormal constituents such as sugar, protein etc… and the frequency of micturitions are to be noted.

The diagnosis is usually arrived by methods of urine examinations called

1. Neerkuri
2. Neikuri. [29]

Collection of Urine:

"அருந்துமாறிரதமும் அவிரோதமதாய்
அஃகல் அலர்தல் அகாலவூன் தவிர்ந்தழற்
குற்றளவருந்தி உறங்கி வைகறை
ஆடிக்கலசத் தாவியே காது பெய்
தொருமுகூர்த்தக் கலைக்குட்படு நிரின்
நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே”
-தேரையர் நீர்க்குறி நெய்க்குறி நூல்

Prior to the day of urine examination, the patient should be advised to take a balanced diet and should have good rest. The first voided urine of the patient is collected in a glass container. The colour, volume, froth, smell, specific gravity and sedimentation are noted. A drop of Gingelly oil is added into the container without any disturbance and the tendency to spread is examined within 1 ½ hrs.

1. Neerkuri:

"வந்தநீர்க்கரியிடை மணநுரையெஞ்சலென்
றைந்திய லுளவையறை குதுமுறை"

In Neerkuri, Niram, Edai, Manam, Nurai and Enjal of the urine voided is noted.

"அருப்பமுற்றார்க் கவ்விதிவிலக்கே" (30)

The following parameters in the urine should be examined.

Niram : It indicates the colour of the urine voided.

Edai : It indicates the specific gravity of urine

(Increased or decreased quantity)

Manam: It indicates the smell of urine voided.

Nurai : It indicates the frothy nature of urine voided

Enjal : It indicates the deposits present in the urine

In addition frequency of micturition, burning micturition, any sedimentation and any associated discharge can be found out.

In *Vellai noi* burning and painful micturition associated with purulent discharge.

ii. Neikuri:

A drop of Gingelly oil is dropped into a wide mouthed glass vessel containing the urine to be tested and kept it under the sunlight in an air free place. The variations of the three thathus in disease can be diagnosed by the behaviour of Gingelly oil on the surface of urine.

Observation

I. Vathaneer:

"அரவென நீண்டினஃதே வாதம்"

A drop of oil dispersed like a snake indicates Vatham (Vali)

II. Pithaneer:

"ஆழி போற்பரவின் அஃதே பித்தம்"

A drop of oil dispersed likes a ring it indicates Pitham (Azhal)

III. Kabaneer:

"முத்தொத்து நிற்கின் மொழிவதென் கபமே"

If the oil drops assumes a pearl shape, it is presumed to be Kabham (Iyam).

IV. Thonthaneer:

"அரவிலாழியும் ஆழியில் அரவும்
அரவின்முத்தும் ஆழியில் முத்தும்
தோற்றில் தொந்த தோடங்களாமே"

When the drop of oil shows two shapes enclosed within one another it indicates thonthaneer.

In *Vellai noi* the neikuri spreads like a ring. By the careful examination of the urine with gingelly oil, the physicians can know whether the disease is curable or not. For this purpose Siddhars have explained various spreading tendencies of oil on urine surface to define the prognosis of the disease. (31)

THINAI (LAND)

Siddhars classified the lands into five types. They are

1.Kurinji – Mountain range
2.Mullai – Pastoral area of the forest
3.Marutham –The fertile river bed
4.Neithal –The coastal region
5.Paalai – Arid desert

Kabha diseases will occur in Kurinji land. Pitha diseases occur in Mullai land.Vadha diseases occur in Neithal land. Staying in Paalai land is not good to health. Marudham land is the fertile area where no disease occurs. So, Marudham land is the best one to stay in.

The winter season gives good health to the man, early summer and later rainy gives moderate health. Whereas early rainy and later summer are more prone to diseases, that's why Siddhars called it as Aanaga kaalam. (32)

RELATION BETWEEN MUKKUTRAM, KAALANGAL AND THINAIGAL

MUKKUTRAM	Paruva kaalam (Seasons)			THINAI
	Thannilai valarchi (Accumulation)	Vaetrunilai valarchi (aggravation)	Thannilai adaithal (Alleviation)	
VATHAM	Mudhuvenil Kaalam	Kaar kaalam	Koothir kaalam	Vatha disease is more prevalent in Neidhal land
PITHAM	Kaar kaalam	Koothir kaalam	Munpani kaalam	Pitha disease is more prevalent in Mullai land
KABHAM	Pinpani kaalam	Elavenil kaalam	Mudhuvenil kaalam	Kabha disease is more prevalent in Kurunji land[33]

PARUVAKALPARUVAKAALAM (Seasonal effects)

Siddhars have classified a year into six seasons each constituting two months. There are some diseases which are more prevalent during a particular Paruvakalam and study of it will be of much useful for diagnosis.

S.No	Perum Pozhuthugal	Synonym	Mukkutra Marupaadugal	Suvai
1.	Kaar kaalam (Aavani & Purattasi) Mid August to Mid October	Early Rainy	VATHAM – Vaetrunilai valarchi PITHAM – Thannilai valarchi	Inippu Pulippu Uppu
2.	Koothir kaalam (Iypasi & karthigai) Mid October to Mid December	Late rainy Autumn	VATHAM – Thannilai adaidhal PITHAM – Vaetrunilai valarchi	Inippu Kaippu Thuvarppu
3.	Munpani kaalam (Margazhi & Thai) Mid December to Mid February	Early Dew Winter Part-I	PITHAM- Thannilai adaidhal	Inippu Pulippu Uppu
4.	Pinpani kaalam (Masi & Pangni) Mid February to Mid June	Later Dew Winter part-II	KABHAM – Thannilai valarchi	Inippu Pulippu Thuvarppu
5.	Elavenir kaalam (Chithirai & Vaikaasi) Mid April to Mid June	Early Summer	KABHAM – Vaetrunilai valarchi	Kaippu Karppu Thuvarppu
6.	Mudhuvenir kaalam (Aani & Aadi) Mid June to Mid August	Late Summer	VATHAM – Thannilai valarchi KABHAM- Thannilai adaithal	Inippu[(34)]

UDAL VANMAI (IMMUNITY)

Siddhars classify udal vanmai into three types.They are

1. Iyarkai vanmai
2. Kaala vanmai
3. Seyarkai vanmai

Iyarkai vanmai

One can inherit his imunity by birth naturally,

Seyarkai vanmai

One can acquire his immunity through various food, activities and medicines.

Kaala vanmai

One can inherit his immunity at different age and different seasons (Paruvakaalam). [35]

UYIR THATHUKKAL / MUKKUTRAM:

The theory mukkutram forms the foundation of Siddha. The primary position is related to the equilibrated state of mukkutram. This definition indicates their importance in the maintenance of health. It can also be summarized that any disturbance in that equilibrated state leads to the development of disease in the body. They are

1. Vali
2. Azhal
3. Kabham

VAATHA

It is the combination of vayu and aakasha boothams. It is responsible for all the movements of the body. It helps in the uniform functioning of 7 Udalthathukkal.

SEATS OF VAATHAM:

Umbilicus, rectum, faecal matters, abdomen, anus, bones, hip joint, naval, plexus, joints, hair follicles and muscles

S.No	Types of vatham	General Features	Changes in *Vellai noi*
1	Piranan (Uyirkkal)	Responsible for respiration and it is necessary for proper digestion.	Normal
2	Abanan (Keel nokkukkal)	Responsible for all the downward forces such as voiding of urine, stools, semen, menstrual flow.	Affected (Constipation, menstrual disturbances)
3	Vyanan (Paravukaal)	Dwells in the skin and is concerned with the sense of touch, extension and flexion of the parts of the body and distribution of the nutrients to various parts of the body	Affected (Tiredness)
4	Uthanan (Melnokkukaal)	Responsible for all kinds of upward mention such as nausea, vomiting etc.,	Normal
5.	Samanan(Nadukkaal)	Considered essential for proper digestion, assimilation and carries the digested nutrients to each and every organ.	Affected (due to other Vayus are affected.)
6.	Nagan	Helps in opening and closing of eyelids.	Normal
7	Koorman	Responsible for vision, lacrimation and yawning.	Normal
8	Kirugaran	Induces appetite,salivation, all secretions in the body including nasal secretion And sneezing.	Normal
9	Thevathaththan	Induces and stimulates a person to become alert, get anger, to quarrel, to sleep etc.,	Affected (Tiredness)
10	Dhananjeyan	Resides in the cranium and produces bloating of the body after death. This leaves from the body after 3 days of death, forming a way through the skull[36]	Normal

AZHAL

This is nothing but the characteristics of fire such as burning, boiling and heating etc. It corresponds to the functions of thermogenesis production of heat necessary to maintain the integrity of the human circulatory systems. Azhal is classified into 5 types. It mainly governs enzymes and hormones.

SEATS OF AZHAL

Between hearts & the naval

Sweat, lymph, blood, stomach, urinary bladder, saliva, eye and the skin.

VARIETIES OF AZHAL

S. No	Types Of Azhal	General Features	Changes In Vellai Noi
1	Analam	Peps up the appetite and aids in digestion.	Affected (Loss of appetite)
2.	Ranjagam	Responsible for the colour and contents of blood.	Anaemia
3.	Saathagam	Controls the whole body and is held responsible for fulfilling a purpose.	Unable to carry out regular works properly
4.	Pirasagam	Dwells in the skin and concerned with the shine, glow, texture and its complexion.	Affected (Itching present in vaginal region)
5.	Alosagam	Responsible for the perception of vision[37]	Normal

KABAM.

It imparts moisture.

SEATS OF KABAM

Above the heart, stomach, fat, sperm, tongue, uvula, bone marrow, blood, nose, nerves, bones, large intestine, eye and joints.

VARIETIES OF KABAM

S. No	Kabam	General Features	Changes In *Vellai Noi*
1	Avalambagam	Lies in the respiratory organs, exercise authority over other kabhas and control the heart and circulatory system.	Normal
2	Kilethagam	Found in stomach as it seat, moistens the food, softens and helps to be digested.	Loss of appetite
3.	Pothagam	Responsible for the perception of taste	Normal
4.	Tharpagam	Presents in the head and is responsible for the coolness of the eyes, sometimes may be referred to as cerebrospinal fluid.	Normal
5	Santhigam	Necessary for the lubrication and the free movements of joints [38]	Affected (Low backache)

UDAL KATTUGAL (SEVEN PHYSICAL CONSTITUENTS)

S. NO	UDAL KATTUGAL	GENERAL FEATURES	CHANGES IN *VELLAI NOI*
1.	Saaram (Digestive essence)	Responsible for the growth and development. It keeps the individual in good temperament and it enriches the body.	Affected (Loss of appetite, Fatigue)
2	Senneer (Blood)	Responsible for the colour of the blood and for the intellect, nourishment, strength of the body.	Affected(Weakness of the body, anaemia)
3.	Oon (Muscle)	Gives lockable contour to the body as needed for the physical activity. It feed the fat next day and gives a sort of plumpness to the body.	Affected (Low Back pain)
4	Kozhuppu (Fat)	Lubricates the organs to facilitate frictionless functions.	Normal
5	Enbu (Bones)	Supports and protects the vital organs, gives the definite structure of the body and responsible for the posture and movements of the body.	Affected (Low Back pain)
6.	Moolai (Bone marrow)	Nourishes the bone marrow and brain which is the center that controls other system of body.	Normal
7	Sukkilam/ Suronitham (Sperm/Ova)	Responsible for reproduction[39]	Normal

Maruthuvam (treatment):

"உற்றா னளவும் பிணியளவுங் காலமுங்
கற்றான் கருதிச் செயல்"

The treatment should be based on the age and body built of the patient, the severity of the disease and the period of the ailment. Siddha system of medicine besides treating the diseases and improves the body condition. This is said as follows:

a. Kaappu (Prevention)

b. Neekkam (Treatment)

c. Niraivu (Restoration)

Kaappu (Prevention):

Siddha system has unequivocally stated that even during the time of conception, some defects creep into the fertilized embryo**,** which forms certain diseases. Those diseases may be cured not only by medicine but by teaching the following habits.

- Teaching good moral habits
- Avoid excessive sex indulgence
- Avoid sex after taking oil bath and curd rice
- Avoid stress and anxiety
- Avoid the use of un hygienic undergarments
- Avoid urinary infection by taking large amount of water
- Avoid increased intake of spicy, sour and salty foods
- Taking oil bath regularly
- Taking laxative once in 6 months
- Always do yoga practice and pranayama according to their physical and mental conditions.

Neekkam (Treatment):

According to Noi Nadal and Noi muthal Nadal a good physician should

Know the deranged kuttram and treat the patients on the basis of altered kuttram.

"முப்பிணி மருவி முனிவுகொள் குறிப்பைத்
தப்பாதறியும் தன்மையும்வாத
பித்தவையம் பிரிவையுமவைதாம்

ஏறியிறங்கி இணைந்துக்கலந்து
மாறி மாறிவரும் செய்கையாற் பிணி
நேர்மை யறிந்து நீட்டுமருந்தே
சீரியதா மெனச் செப்புவர் சித்தரே"[40]

The aim of treatment is based on

- Bringing of tridosham to normal
- Treat the disease according to the symptoms

For normalizing Tridosham:

"விரேசனத்தால் வாதம் தாழும்
வமனத்தால் பித்தம் தாழும்
நசிய அஞ்சனத்தால் கபம் தாழும்"

- Vatha diseases can be brought down by "viraesanam". For this laxatives and purgatives are given according to patient's tolerance to drug and also the severity of the disease should be assessed.
- Pitha diseases can be brought down by giving "vamanam" and kabha diseases can be brought down by "Anjanam" and "Nasiyam".
- In Vellai noi pitham is altered as well as vatham. So laxative is administered on the first day or before starting the specific treatment.

MANAGEMENT

"விரேசனத்தால் வாதம் தாழும்"

For Purgation: Mega naatha Thailam.

After rearrangement of doshas: Aghil kattai chooranam – 1 gm, 2 times / day with Butter. [41]

Pathiyam:

During the course of the treatment, the patient is advised to follow certain precautions regarding diet and physical activities. This form of medical advice in Siddha system of medicine is termed as "PATHIYAM" which is very important in Siddha system of medicine.

"பத்தியத்தினாலெ பலனுண்டாகும் மருந்து
பத்தியங்கள் போனால் பலன்போகும்-பத்தியத்தில்
பத்தியமே வெற்றி தரும் பண்டிதருக் காதலினாத
பத்தியமே உத்தியென பார்"

Itchapathiyam:

"கடுகிநற்றிலத் தெண்ணெய்கூழ்ப் பாண்டங்கள் கடலை
வடிவதாகிய தெங்குமா வருக்கைநற் காயம்
மடிவிலாதவெள் ளுள்ளிகொள் புகையிலை மதுபெண்
இடதுபாகலோ டகத்திநீக் கிடலிச்சா பத்தியம்

Pathiyam (diet) for Pitha disease:

Pathiyam for pitha disease as mentioned in Patharthaguna chindamani is as follows:

"கொம்மட்டி வாழைப்பன்னாங் கொளுத்திய கரியி நோடே
விம்மிய தண்ணீர்விட்டான் வேரெனுங் கிழங்கு சாந்தஞ்
செம்மைசேர் நெல்லிமுள்ளி சேருமில் மருந்தெல்லாமே
கம்மிய மித்தத்திற்கு காலலென் றோது வாரே"[42]

Niraivu (Restoration of wellbeing):

- Reassurance of recovery was given to every patient.
- Every patient was advised to follow strict diet restrictions, good moral behaviour.

DIET AND ADVICE:

The following diet to be taken:

- Drink adequate water
- Leafy greens & vegetables
- Lady's finger
- Onion
- Lemon or orange juice
- Apple
- Black plums

- Pears
- Gooseberry
- Dates
- Fig fruit
- Pome granate
- Grapes
- Guava
- Whole wheat
- Brown rice
- Milk
- Butter milk
- Ghee

The following food should be avoided:

- Chicken
- Meat
- Coconut
- Jack fruit
- Mango
- Brinjal
- Sesbanian leaves
- Mustard
- Sesame
- Tea
- Coffee
- Preserved cool drinks
- Oily & fried foods
- Sour foods

AVOID:

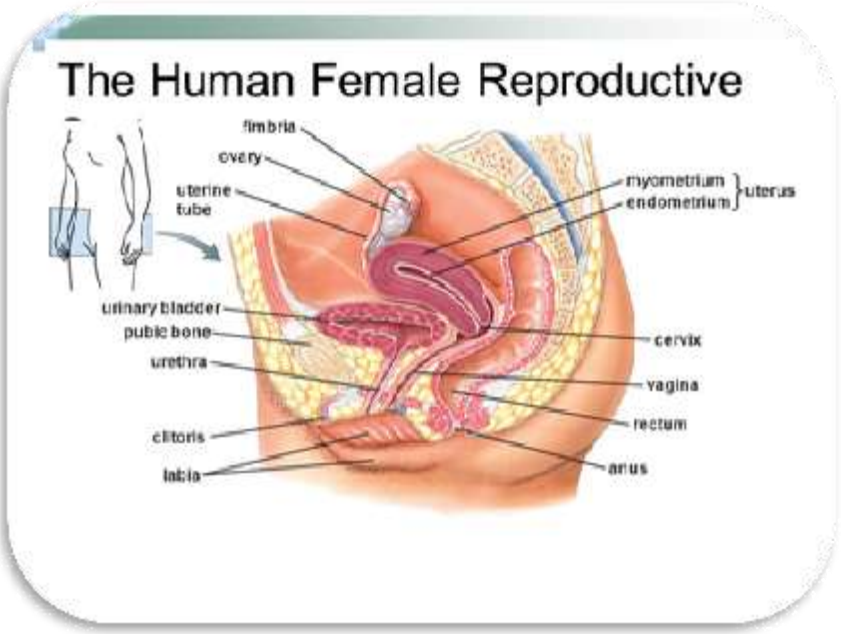
- Tobacco
- Alcohol
- Excessive lust

MODERN ASPECT

DEFINITION:

The term *leucorrhoea* should be restricted to those conditions when the normal vaginal secretion is increased in amount. In such patients there will be no excess of leucocytes present when the discharge is examined under the microscope, and the discharge is macroscopically and microscopically non-purulent. Purulent discharges due to specific infections such as *Gonorrhea*, *Trochomoniasis* and *Moniliasis*, ulcerated growths of the cervix and the vagina and discharges caused by urinary fistulae are of a different type and should be excluded from the term leucorrhoea. Some clinicians use the term to describe any white or yellowish-white discharge from the vagina.

ANATOMY OF THE FEMALE REPRODUCTIVE SYSTEM

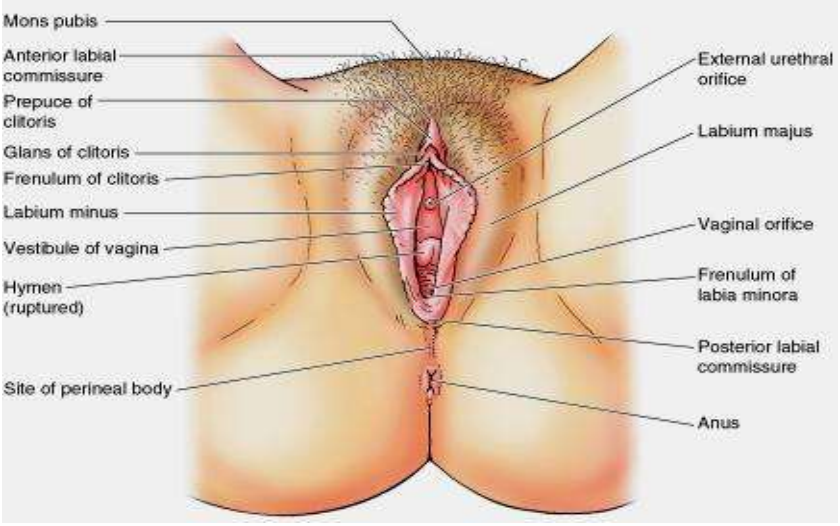


The female reproductive system can be divided into the external and internal genitalia. The external genital organs are vulva. The internal genital organs are vagina, uterus, cervix, fallopian tubes, ovaries and other supporting structures.

The vulva is an ill-defined area, which comprises the following structures.

- The Mons pubis
- The Labia majora
- The Labia minora
- The Clitoris
- The Vestibule
- The External meatus
- Bartholin's gland.
- The Hymen
- The Navicular fossa
- The Fourchette

EXTERNAL FEMALE GENITAL ORGANS



The Mons pubis:

It is the pad of subcutaneous adipose connective tissue lying in front of the pubis and in the adult female, is covered by hair.

The Labia Majora:

The labia majora pass from the mons veneris to end posteriorly in the skin over the perineal body. They consist of folds of skin which enclose a variable amount of fat and are best developed in the child-bearing period of life. In children before the age of

puberty and in postmenopausal women, the amount of subcutaneous fat in the labia majora is relatively small and the cleft between the labia is therefore conspicuous. At puberty, pudendal hair appears on the mons veneris, the outer surface of the labia majora and in some cases on the skin of the perineum as well. The inner surfaces of the labia majora are hairless and the skin of this area is softer, moister and pinker than over the outer surfaces. The labia majora are covered with squamous epithelium and contain sebaceous glands, sweat glands and hair follicles. There are also certain specialized sweat glands called apocrine glands, which produce a characteristic aroma and from which the rare tumour of hidradenoma of the vulva is derived. The secretion increases during sexual excitement.

The Labia Minora

The labia minora are thin folds of skin which enclose veins and elastic tissue and lie on the inner aspect of the labia majora. The vascular labia minora are erectile during sexual activity; they do not contain any sebaceous glands or hair follicles. Anteriorly they enclose the clitoris to form the prepuce on the upper surface and the frenulum on its undersurface. Posteriorly they join to form the fourchette.

Clitoris:

The clitoris is an erectile organ and consists of a glans, covered by the frenulum and prepuce, and a body which is subcutaneous; it corresponds to the penis and is attached to the undersurface of the symphysis pubis by the suspensory ligament. Normally, the clitoris is 1-11/2cmlong and 5mm in width. Clitoris of more than 3.5 cm in length and 1 cm in width is called clitoromegaly, and occurs in virilism due to excess of androgen hormone. The clitoris is well supplied with nerve endings and is extremely sensitive. During coitus it becomes erect and plays a considerable part in inducing orgasm in the female. The clitoris is highly vascular. An injury to the clitoris causes profuse bleeding and can be very painful.

Vestibule:

The vestibule is the space lying between the anterior and the inner aspects of the labia minora and is bounded posteriorly by the vaginal introitus.

External meatus:

The external urinary meatus lies immediately posterior to the clitoris. The vaginal orifice lies posterior to the meatus and is surrounded by the hymen.

Bartholin's gland:

Bartholin's gland lies posterolaterally in relation to the vaginal orifice, deep to the bulbospongiosus muscle and superficial to the outer layer of the triangular ligament. It is embedded in the erectile tissue of the vestibular bulb at its posterior extremity. It is normally impalpable when healthy, but can be readily palpated between the finger and the thumb when enlarged by inflammation. Its vascular bed accounts for the brisk bleeding which always accompanies its removal. Its duct passes forwards and inwards to open, external to the hymen, on the inner side of the labium minus. The gland measures about 10mm in diameter. The function of the gland is to secrete lubricating mucous during coitus.

Hymen:

The vaginal orifice lies posterior to the meatus and is surrounded by the hymen. In virgins, the hymen is represented by a thin membrane covered on each surface by squamous epithelium. Coitus results in rupture of the hymen.

Navicular fossa:

The fossa navicularis is the small hollow between the hymen and the fourchette.

Fourchette:

The fourchette is a thin fold of skin, identified when the labia are separated, and it is often torn during parturition.

The external genital organs have three main functions:

- Enabling sperm to enter the body
- Protecting the internal genital organs from infectious organisms
- Providing sexual pleasure[43]

INTERNAL GENITALIA

VAGINA:

The vagina is a tubular, muscular canal extending from the hymenal orifice below to the cervix uteri above. As it is attached to the cervix slightly higher up posteriorly, the posterior vaginal wall is longer (10-11 cm) and the posterior fornix deepest compared to the anterior vaginal wall which is about 8 cm, Its anterior and posterior walls are ordinarily close together except in its upper part where it is most distensible. The direction of the vaginal canal is slightly curved and directed upwards and backwards. The vaginal walls are thrown into transverse folds or rugae in nulliparous women but in the multiparae they are usually stretched out. In the anterior vaginal wall, three transverse sulci establish themselves as important landmarks; below the external urinary meatus, at the vesico – urethral junction, and near the vagino – cervical junction where the bladder is attached to the anterior vaginal wall. (44)

Functions of the vagina

1. Female copulatory organ
2. Semen is deposited in the upper vagina
3. It is the canal for child birth
4. Menstrual blood is discharged out through the vagina.
5. It inhibits infections in female during the reproductive age.

Sphincters of vagina

1. Pubo vaginalis muscle
2. Urogenital diaphragm
3. Bulbo spongiosus muscle. (45)

Normal Vaginal Flora:

Resident vaginal flora consists of a combination of both aerobic and anaerobic organisms. The microflora of normal vaginal secretions is characterized by a predominance of lactobacilli, primarily acidophilic lactobacilli. Usually, an additional

5 to 15 bacterial species are also normally cultured from the vagina G. vaginalis can be found in >50% of normal, healthy women.

Common aerobic facultative organisms found include lactobacilli, staphylococcus epidermis, streptococci and G. Vaginalis. The anaerobic organism commonly found includes Bacteroides species, B.bivius and Peptostreptococcus.

Mycoplasma hominis can be found in 20% to 50% and Ureaplasma urealyticum can be found in 50% to 70% of sexually active women. In women with normal vaginal flora, lactobacillus species account for >95% of the total organisms present. [46]

The vaginal secretion:

The vaginal secretion is small in amount in healthy women and consists of white coagulated material. When it is examined under the microscope, squamous cells which have been shed from the vaginal epithelium and Doderlein's bacilli alone are found. **Doderlein's bacillus** is a large gram – positive rod- shaped organism, which grows anaerobically on acid media. The vaginal secretion is acidic due to the presence of lactic acid, and this acidity inhibits the growth of pathogenic organisms. The pH of the vagina averages about 4.5 during reproductive life. The acidity, which is undoubtedly oestrogen – dependent, falls after menopause to neutral or even alkaline. Before puberty, the pH is about 7. This high pH before puberty and after menopause explains the tendency for the development of mixed organism infections in these age groups.

The synthesis of lactic acid is probably influenced by either enzyme or bacterial activity(Doderlein) on the glycogen of the epithelial cells which itself is dependent on the presence of oestrogen, so that its deficient activity can be boosted by the administration of oral or local oestrogen. During the puerperium and also in cases of leucorrhoea, the acidity of the vagina is reduced and pathogenic organisms are then able to survive. The squamous cells of the vagina and cervix stain a deep brown colour after being painted with iodine solution, owing to the presence of glycogen in healthy cells (positive Schiller's test). The abnormal and malignant cells do not contain glycogen and do not take up the stain. Similarly, these abnormal cells turn white with

acetic acid due to coagulation of protein. These areas are selected for biopsy in the detection of cancer. [47]

Vaginal acidity

The vaginal acidity is due to lactic acid, which may be present as much as 0.6%. The pH value is 5.7 in the new – born and reaches 6-8 in children, and falls to 4 at puberty. During pregnancy the pH value is usually 4. After the menopause the pH rises to 7. The normal pH in healthy women during the childbearing period is about 4.5.

It is important to understand that Doderlein's bacillus is almost the only organism which will grow at a pH of 4- 4.5. As the acidity of the vagina falls and the pH rises, non- resident pathogens are able to thrive.

Natural defence mechanism of the vagina against infection:

The skin of the vagina is a tough stratified squamous epithelium devoid of glands. It presents a smooth unbroken surface to the attack of pathogenic organisms. There are no crypts where organisms can comfortably multiply as in the endocervix. The pH is low and the high acidity mitigates against bacterial growth. The thickness of the armour, the epithelium and the hostile pH depend upon oestrogen, and therefore, it is only in extreme youth before puberty and in senescence, i.e. after the menopause, that bacterial inroads are likely. There are certain times when the pH is raised:

- During menstruation when the cervical and the endometrial discharge, which is alkaline, tends to neutralize the vaginal acidity.
- After abortion and labour when the alkaline lochia has a similar effect.
- An excessive cervical discharge, such as occurs in endocervicitis, has the same effect.

Apart from these exceptions, the vagina is naturally self-sterilizing.

- Doderlein's bacilli maintain the normal ecosystem in the vagina.[48]

Changes in the vaginal epithelium in different periods of life:

1. **During childhood**
    a. Columnar epithelium lining it

b. Bacteria called Doderlein's bacilli and glycogen are absent in the vaginal mucosa.

2. **During reproductive age**
   a. Stratified squamous epithelium lining it
   b. Doderleins bacilli and glycogen are present. Doderlein bacilli convert glycogen in to lactic acid.
   c. The reaction is acidic. Lactic acid maintains vaginal pH acidic. Superficial cells are exfoliated.
   d. During oestrogenic phase of menstrual cycle there is proliferation and more cornification.
   e. During progesteronic phase of menstrual cycle there is more proliferation and less cornification.
3. **During pregnancy**

   Navicular cells or pregnancy cells are present.

4. **After menopause**

   Atrophy of the mucous membrane. [49]

UTERUS:

The uterus is a hollow, strong, musculoglandular organ of the female body.

Situation

It lies between the urinary bladder and rectum, within the pelvis.

Development

Para mesonephric ducts.

Shape

Inverted pear shape.

Communications

Through the uterine tubes, it communicates with the peritoneal cavity. Through the vagina, it communicates with the exterior.

Position

Normal uterus is situated in the anti-verted and anti-flexed position.

Anti-flexion – This is the angulation between the body and cervix of the uterus. It is about 120^{o}

Anti-version – The angulation between the long axis of the uterus and vagina. It is about 90^{o}

Parts of the uterus

1. Fundus
2. Body
3. Cervix [(50)]

Age changes in the uterus

Foetal uterus

Pelvis is not developed well. So uterus is found in the lower abdomen. Cervix is longer than the body of uterus.

Pubertal uterus

The uterus acquires its normal anatomical position. The body of the uterus grows faster and longer than the cervix. The uterus is an abdominal pelvic organ.

During menstrual period

The uterus is enlarged. The endometrium is thickened and highly vascular.

Uterus during pregnancy

Gradual enlargement of the uterus so that at terminal stage of pregnancy the fundus is situated in the epigastric region. The lumen of the uterus is abnormally increased to 5000 -7000 ml capacity and weighing about 1000 grams.

Uterus after parturition

Uterus regresses, its size gradually so that after the 8^{th} week of delivery it appears, somewhat normal.

Uterus at menopause

The organ is very much reduced in its size. Obliteration of internal and external os occurs

Functions of the uterus

1. Menstrual cycle
2. Conduction of sperm
3. Implantation of zygote and further development of pregnancy.
4. The cervix provides an alkaline secretion which helps in the conduction of sperm.
5. Cervix acts as a sphincter during pregnancy.
6. Labour – during childbirth the body of the uterus contracts whereas the cervix relaxes. (51)

CERVIX:

The cervix is about 2.5 cm in length and in diameter and is divided equally into the vaginal and supra- vaginal portions. The vaginal portion protrudes into the vaginal vault to form the anterior, lateral and posterior fornices. It is a firm, fibromuscular structure through which the spindle shaped cervical canal traverses and opens below into the vagina at the external os. The canal communicates above with the uterine cavity at the internal os. The mucus membrane of the vaginal portion is continuous with that of the vagina. The endocervical lining is columnar and in some areas it forms folds or crypts extending into the muscular tissue to form mucus – producing 'glands', It is now known that these are infoldings of the mucus- secreting membrane. The clear mucus secretion from the cervix is thinnest and most abundant at the time of ovulation, thus facilitating sperm migration. It also gives rise to ferning in the follicular phase; this palm leaf pattern is destroyed by the progesterone in the luteal phase of the menstrual cycle. In these crypts, gonococci may be harboured and can give rise to gonococcal cervicitis.

The external os is circular in nulliparae but during parturition the circular muscle fibres at the external os tear to produce a slit- like appearance and give rise to the anterior and posterior lips of the cervix.

The external os is the site of the junction between the columnar and the squamous epithelium. The vaginal part of the cervix around the os, in certain conditions shows evidence of erosion or replacement of the thick squamous epithelium with the thin columnar epithelium of the endocervix. Similarly the chances of severe dysplasia, carcinoma – in-situ and invasive squamous cell carcinoma are relatively high at this site. Squamous cell carcinoma arising in this area is the most common type of cancer among women in India. Perhaps this may be due to the interplay of different forces – hormones, infections, inflammation and trauma – at this site. (52)

UTERINE TUBES:

Each uterine tube lies in the free margin of the corresponding broad ligament. It has medial and lateral ends. The uterine tube is about 10 cm long. About 1 cm of the tube, near the medial end, is embedded in the muscle wall of the uterus: this is the uterine part of the tube. The next 3 cm or so is thick – walled and has a narrow lumen so that it is cord like: this part is called the isthmus. The next 5 cm or so is thin walled and has a much larger lumen than the rest of the tube. This dilated part is called the ampulla. The lateral end of the uterine tube is funnel shaped and is called the infundibulum. The walls of the infundibulum are prolonged into a number of irregular processes called fimbria. One of this fimbria is larger than the others and is in close contact with the ovary. It is called the ovarian fimbria.

In the nulliparous woman the uterine tube comes into contact first with the lower pole of the ovary; then ascends along its anterior border to reach the superior pole. It finally descends to partially cover the medial surface of the ovary.

Ova discharged from the ovary enter the uterine tube through the infundibulum and pass into the ampulla. They slowly travel towards the uterus. If sexual intercourse takes place at the appropriate time spermatozoa enter the uterine tube through the vagina and uterus and meet the ovum in the ampulla of the tube: fertilization normally takes place here. The fertilized ovum travels through the uterine tube towards the uterus to enter its cavity. Here it gets implanted in the uterine wall. If fertilization does not occur the unfertilized ovum enters the uterus and is discharged through the vagina. (53)

OVARIES:

The ovaries are female gonads. They are homologous to the testis in male. A pair of ovaries is situated within the pelvis.

Shape

Oval shaped

Colour

Dull white

Situation

Ovarian fossa. This fossa is situated in the lateral pelvic wall. (54)

LEUCORRHOEA

DEFINITION:

Literally, leucorrhoea means white discharge. It includes conditions when the vaginal discharge is excessive and associated with or without any obvious local pathology, in practices all excessive vaginal discharge, white, purulent, yellowish or watery, but not blood – stained, is labelled Leucorrhoea. (55)

PREVALENCE:

Vulvovaginal *Candidiasis* affects about 75% of women at some time during their reproductive life, with 40 - 50% having two or more episodes. Bacterial vaginitis is also very common, but as 50% of cases of bacterial vaginitis are asymptomatic, the true prevalence of this condition in the community is uncertain.

Many authors have documented vaginal discharge as one of the commonest symptom of genital tract disease reported by women in India. (56)

ETIOLOGY:

The causes of leucorrhoea may be physiological or pathological. The physiological causes are puberty (due to increased vascularity), ovulation (due to increased cervical mucus), the premenstrual period (owing to the increased secretion

of the endometrial glands) and pregnancy (increased vascularity). The pathological causes are several general or local conditions. In severe Anaemia, congestive cardiac failure, debilitating diseases and ascites the patient may complain of Leucorrhoea, but examination of the vagina and discharge shows no obvious local pathology requiring specific treatment for this complaint.

The local causes of leucorrhoea are:

1. Pelvic tumours such as fibroids, ovarian neoplasms and PID, which may cause excessive discharge due to the increased blood supply to the pelvic organs.

2. Cervical lesions which occur as a result of excessive mucus discharge from the endocervical glands in chronic endocervicitis, cervical erosion, polyp and ectropion. The patient complains of excessive mucoid discharge or 'mucorrhea' cervical erosion is a misnomer as strictly speaking there is no erosion or ulcer; the thick multi-layered squamous epithelium is replaced by a single – layered columnar epithelium.

3.Vaginitis, which may be specific due to infections caused by sexually transmitted diseases (STD) such as *gonorrhoea*, *protozoal o*rganisms such as *Trichomonas vaginalis*, and fungi such as *Candida albicans*; or non – specific due to infection through mixed organisms such as *Strepto coccus, Staphylococcus*, *Hemophilus vaginalis, E. coli* or anerobes. This latter condition is seen in women using pessaries, tampons and other foreign bodies and chemicals, and in postmenopausal women. [57]

PATHOPHYSIOLOGY:

Flora of the female genital tract

In healthy women the fallopian tubes, the cavity of the uterus and the upper third of the cervical canal are free of microorganisms. The lower third of the cervical canal always contains micro-organisms, as does the vagina. In healthy women the Doderlein's bacillus is the only organism found in the upper two-third of the vagina, but in the neighbourhood of the vulva both saprophytic and parasitic organisms can be demonstrated. Doderlein's bacilli have been found in the vagina of the new born within 9 hours after delivery, although the usual time for them to appear is 15 hours. The vagina of the new born is probably inoculated during parturition.

During the puerperium, acidity of the vagina is reduced and foreign organisms such as coliform bacilli and other pathogens can grow.

Vaginal discharge increases around ovulation, during pregnancy and intercourse. Antibiotics and barrier contraceptives also make vaginal secretion more alkaline and conduce to increased secretion.

During the climacteric and after the menopause, the number of Doderlein's bacillus is reduced and sometimes this organism cannot be demonstrated in the vagina. The importance of Doderlein's bacillus is that its presence is associated with the production of lactic acid contained in the vagina and this acidity inhibits the growth of other organisms. In multiparous women when the vaginal orifice is patulous as a result of lacerations during childbirth, foreign organisms may be found in the lower part of the vagina which by producing a low-grade vaginitis give rise to discharge.[58]

The vaginal secretion is very small in amount and is sufficient to make the surface moist. The secretion is mainly derived from the glands of the cervix, uterus, transudation of the vaginal epithelium and Bartholin's glands. Normally it is dependent on the endogenous oestrogen level with increases oestrogen level, there is abundant secretory activity of the endocervical glands and the superficial vaginal epithelial which is rich in glycogen.

There is increased secretion due to 3 causes.

a) Physiological Excess: Normally it is increases when oestrogen level in the body increases such as during puberty, during menstruation, around ovulation, during pregnancy due to hyperestrinism during sexual excitement (Abundant secretion from the bartholins glands)

b) Cervical Cause: In some like cervical ectopic, chronic cervicitis, mucous polyp's etc. non infective cervical lesion may produce excessive secretion which pours out in vulva.

c) Vaginal Causes: Increased Vaginal Transudation occurs along with pelvic congestion.

The condition like uterine prolapse, chronic prolapse inflammation, pill user etc. Ill health produces excess exfoliation of the superficial cells.

CLASSIFICATION

Types of leucorrhoea:

Abnormal vaginal discharge

I. Non-infective

1. Vaginal cause

- Uterine prolapse
- Acquired Retroverted uterus
- Chronic pelvic inflammation
- Pills use
- Vaginal adenitis

2. Cervical cause

- Cervical ectopy
- Mucous polyp
- Ectropion
- Chronic Cervicitis

II. Non-purulent, Non-offensive, Non-irritant

- Physiological
- Cervical cause
- Vaginal cause

III. Infective

- Tricomonas vaginalis
- Candida albicans
- Gardnerella vaginalis
- Neisseria gonorrhoeae
- Chlamydia trachomatis

IV. Neoplastic

V. Foreign body.

NON-INFECTIVE LEUCORRHEA:

Physiological cause:

An increase in the normal vaginal secretion develops physiologically at puberty, during pregnancy, at ovulation and, in some women, during the premenstrual phase of the menstrual cycle. During pregnancy the normal discharge is increased in amount because of the vascularity of the female genital tract. During the latter part of menstrual cycle, the hypertrophied premenstrual glands of the endometrium secrete mucus which is discharged through the cervix into the vagina. The leucorrhoea of puberty is probably caused by the increased vascularity of the uterus, cervix and vagina at that time. It is of temporary duration and needs no treatment. This secretion contains proteins, polysaccharides, amino acids, enzymes and immunoglobulin.

Specific leucorrhoea:

Any vaginal discharge which is frankly purulent and contains pus cells from which the causative organisms can be isolated and cultured should be considered as due to specific vaginal infection.

Specific vaginitis comprises of:

- Gonoccoccal
- Trichomonal
- Monilial
- Chlamydial and
- Bacterial vaginosis. [59]

CANDIDAL (MONILIAL) VAGINITIS

It is a fungal infection caused by yeast – like microorganisms called *Candida* or *Monilia*. The commonest species causing human disease is *Candida albicans*, which is gram positive and grows in acid medium. It may be sexually transmitted. Almost 25% women harbour *Candida* in the vagina; these are often asymptomatic. [60]

EPIDEMIOLOGY:

Candida albicans responsible for *candidosis* is commensal in the genitals in health, but may turn pathogenic under favourable conditions like pregnancy, malnutrition, diabetes and on treatment with wide-spectrum antibiotics, immunosuppressive drugs and oral contraceptives. It may affect males and females of any age group. Hot humid climate and unhygienic conditions may favour the infection. (61)

RISK FACTORS:

These include promiscuity, immunosuppression, HIV women pregnancy, and steroid therapy, following long- term broad – spectrum antibiotic therapy, oral contraception pills, diabetes mellitus, poor personal hygiene and obesity.

CLINICAL FEATURES:

Pruritus vulva is the cardinal symptom. It is often accompanied by vaginal irritation, dysuria, or both, and passage of thick curdy or flaky discharge. Speculum examination reveals vaginal wall congestion with curdy discharge often visible at the vulval mucocutaneous junction and in the posterior fornix.

DIAGNOSIS:

It is essentially based on clinical findings. But the diagnosis can be conformed on microscopic examination of a smear of the vaginal discharge treated with 10% KOH solution, which dissolves all other cellular debris, leaving the mycelia and spores of the *Candida* in bold relief. Gram staining of the discharge or Pap smears may also reveal presence of *Candida*. Culture on Sabouraud's agar or Nickerson's medium helps to identify *Candida.*

Pap smear shows thick red – stained hyphae and dark red spores. The colonies on culture appear as black rounded colonies 1-2 mm in diameter with yeast – like odour.

Vaginitis test (wet mount): a sample of vaginal discharge is taken and a slide made for microscopic examination

TREATMENT:

Local intravaginal application of antifungal agents like imidazole, miconazole, clotrimazole, butoconazole or terconazole vaginal pessaries or creams used for 3-6 days is very effective. A single dose of fluconazole 150mg has been found to be very effective. Ideally, both partners should be treated and the underlying predisposing factor corrected to give long – term relief. Recurrent infection requires fluconazole orally 150 mg every 72 hours for 3 doses and then weekly for a few weeks.

- Nystatin pessary, bd × 10 days
- Miconazole cream 2% × 7 days
- Clotrimazole 100 mg vaginal tablet × 7 days or 1 % cream for 7- 10 days
- Ketoconazole 400 mg daily × 5 days [(62)]

GARDNERELLA (BACTERIAL) VAGINOSIS

Bacterial vaginosis is termed *vaginosis* rather than *vaginitis*, because it is associated with alteration in the normal vaginal flora rather than due to any specific infection. There is a considerable decrease in the number of lactobacilli in the vaginal discharge with 100- fold increase in growth of other anaerobic bacteria. Since lactobacilli reduce pH and release hydrogen peroxide toxic to other bacteria, reduction in their number allows other bacteria, i.e. aerobic and anaerobic bacteria, to grow. These are *Haemophilus vaginalis, Gardnerella, Mobiluncus* and *Mycoplasma hominis*.

Mobiluncus is a gram-positive rod-shaped bacterium with a characteristic corkscrew spinning anaerobe. The bacterial vaginosis is therefore a polymicrobial condition.

It is not sexually transmitted with a variable incubation period. About 50% women are asymptomatic carriers of infection, but majority complain of vaginal discharge without itching.

The characteristics of vaginal discharge are as follows:

- White, milky non-viscous discharge adherent to the vaginal wall.
- pH of the discharge is more than 4.5
- Fishy odour when mixed with 10% KOH is due to amino- metabolites from various organisms.
- Presence of *clue cells* – the epithelial cells have fuzzy border due to adherence of bacteria.
- Increased number of *Gardnerella vaginalis* and other organisms and reduced number of lactobacilli and leucocytes.
- Gram stain and culture are additional investigations.

  The woman has minimal vulval irritation. The diagnosis is based on wet smear and culture. The smear reveals clean background with few inflammatory cells and other organisms, but scanty lactobacilli. Many epithelial cells present a granular cytoplasm caused by small gram – negative bacilli adhering on their surface, so-called *clue cells.* Free floating clumps of *Gardnerella* are seen.

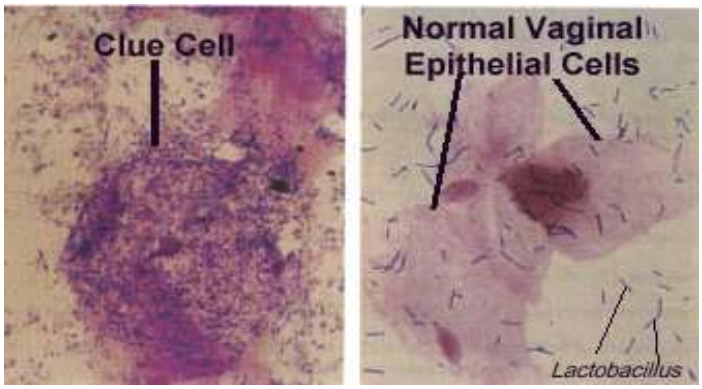
This infection can cause PID, chorioamnionitis, premature rupture of membrane and preterm labour. [(63)]

DIAGNOSIS

BV, characterized by a foul – smelling discharge, can be diagnosed microscopically or clinically. The discharge is primarily sloughed epithelial cells, many of which are completely covered by tiny, gram – variable rods and coccobacilli. These cells are called clue cells. The absence of inflammatory cells in the vaginal discharge is another sign of BV. Although *Gardnerella vaginalis has* been historically associated with the syndrome and can be cultured on a human blood bilayer plate, culture is not recommended for diagnosis of BV. A clinical of BV is best made using three or more of the following criteria: homogeneous, gray discharge; clue cells seen

on wet mount or Gram stain; a pH greater than 4.5; and an amine or fishy odour elicited by the addition of a drop of 10% KOH to the discharge on a slide or on the speculum.

Probably the best way to differentiate BV from other vaginal infections is by Gram stain. Nugent and colleagues has developed a grading system for Gram stains of vaginal discharge. This system is based on the presence or absence of certain bacterial morphologies. Typically, in patients with BV, lactobacilli are either absent or few in number, whereas curved, gram- variable rods and/ or *G.vaginalis* and *Bacteroides* morphotypes predominate. The Gram stain is more sensitive and specific than either the wet mount for detection of clue cells or culture for *G.vaginalis,* and the smear can be saved and reexamined later. (64)



TREATMENT:

The 7-days course of metronidazole 500mg twice daily is effective in 85% cases, whereas a single dose of 2g cures only 45%. Ampicillin 500mg or cephalosporin 500mg bid for 7days is also effective. Tetracycline 500mg four times a day, doxycycline 100mg twice a day and sulphafurazole 1g four times daily for 10-14 days are the alternative antibiotics.

Clindamycin 2% cream locally is effective in 85%. Oral clindamycin 300 mg daily for 7 days is effective. Ornidazole 500mg vaginal tablet daily for 7 days is also effective. Vaginal tablet avoids first-pass effect in liver seen with oral route.

Lacteal is protein-free acidifying lactate gel which neutralizes the vaginal

PH-5ml is applied daily for 7 days.

The infection recurs in 30%.

Metronidazole does not reduce the number of lactobacilli unlike clindamycin and may be considered superior to the latter. [65]

VAGINITIS

Vaginitis is an important cause of leucorrhoea and is therefore considered in detail below:

Gonococcal vulvo – vaginitis:

In the reproductive age, *N.gonorrheae* mainly causes Bartholinitis, urethritis and cervicitis besides salphingitis but no vaginitis because the thickness and acid medium of the vagina protects against *N.gonorrheae*. In children and menopausal women in whom the vaginal epithelium is thin, *gonococcal* organisms can easily attack the vaginal mucosa to cause vaginitis. Since it is sexually transmitted, the source of infection must be traced and the carrier treated. The purulent discharge on examination with a Gram stain will show Gram – negative intracellular *diplococci*. Preparation of a culture may be helpful. The treatment in uncomplicated *gonococcal* urogenital infections consists of: Amoxicillin 3 g with 1 g Probenecid orally or Ampicillin 3.5 g with 1 g Probenecid or Doxycyidine Hcl 100 mg orally twice daily for a week.

Norfloxacin 800 mg single dose orally has also been used successfully. The sexual partners and their contacts should be treated on similar lines.

Vaginitis due to *Chlamydia trachomatis*

This is another STD which causes vaginitis and urethritis. The patient complains of dysuria and mucopurulent discharge. It is seen in 25-40 percent of the female partners of men suffering from non- gonococcal urethritis. The smear is negative with a Gram stain but with special cytological staining (for example Giemsa), tissue culture and serological tests, diagnosis is possible. The patient and her sexual partner are treated with Doxycycline 100 mg orally daily for seven days.

Trichomoniasis:

Perhaps the most common and the most important cause of vaginitis in the reproductive age is vaginal *Trichomoniasis*. It is caused by *Trichomonas vaginalis*, a flagellated protozoan organism which is about 10µm long and 7µm in width (or slightly larger than a leucocyte) and is an anaerobe. It is actively motile. Sexual intercourse is the main means of transmission of this organism and it is hence considered an STD. Men harbour it in the urethra and prostate.

T.vaginalis causes a profuse, thin, frothy, yellowish or greenish discharge (due to the myeloperoxide pigment of the polymorphonuclear leucocytes) containing thousands of polymorphs per mm^3. The vaginal walls including the portio vaginalis are tender and congested. There is associated dysuria and pruritis. The pH of the discharge is over 5. A saline wet mount shows motile trichmonads in over 80 per cent of cases. It can also be grown in culture in over 90% of them and is useful in smear-negative patients. The treatment consists of oral administration of metronidazole 200 mg thrice daily for a week is effective. Failures are due to reinfection especially after the menstrual periods.

Vaginitis due to oestrogen deficiency:

This may be of two kinds:

1. Vulvo- vaginitis in children, as stated earlier, may be due to *N.gonorrheae* but is often due to *E.coli*, *Staphylococci* and others. It may be caused by contamination from extraneous sources: from an adult or another child, by the use of infected clothes or the insertion of a foreign body in the vagina. The vulva is reddish with a purulent or blood-stained discharge and the child may be seen constantly scratching the external genitals. Examination under anaesthesia is needed to detect (and remove) any foreign body besides obtaining the smear for investigation and treatment. Local estrogenic cream and specific chemotherapy (depending on the organisms) are useful.

2. Senile vaginitis:

Due to oestrogen deficiency, the thin atrophic vagina may be infected by mixed pathogens, *N.gonorrheae* or even *T. vaginalis*. There is blood-stained discharge from

the inflamed vagina. Vulvitis too is present because of the pruritus. Sometimes a forgotten pessary may be the cause.

In these cases, the smear has to be examined for the causative organism. Malignancy has to be ruled out by examination of these patients under anesthesia, by a study of Pap smear, fractional curettage and cervical biopsy. The foreign body if any has to be removed. When the discharge is foul-smelling, an infected malignant growth from the cervix or rarely a pyometra may have to be ruled out.

The treatment consists of small doses of estrogens. Premarin 0.625 mg a day orally for a week, local estrogenic cream and any specific antibiotics depending on the organism have to be administered. Douches are contraindicated. In vaginitis, strong antiseptic solutions should never be used for cleaning the vagina. Non –irritant normal saline or plain water is useful for vaginal irrigation.

Leucorrhoea due to cervical polyps, a foreign body, chemicals, contraceptive creams and urinary fistulae are all secondary, and the treatment depends on the cause. (66)

COMPLICATIONS:

Candida albicans can reside deep in the vaginal epithelium, protected from tropical antifungal therapy, only to surface at a later date and cause a re-infection. Vulvovaginal candidiasis may increase the rate of sexual transmission of HIV. Vaginitis may be early and prominent feature of toxic shock syndrome. A very rare complication of candida vaginitis is wide dissemination of the parasites to produce a dangerous systemic infection.

Having sex with someone who has bacterial vaginosis, as well as having multiple sex partners or a new sex partner, can put you at risk for the infection and says shuford. Douching can also increase the risk, as it disrupts the balance of bacteria in the vagina. The complications and health risks of bacterial vaginosis can be serious if the infection isn’t treated.

Untreated vaginosis can lead to:

- Pelvic inflammatory disease
- Infertility and ectopic pregnancy
- Pregnancy complications- low-birth-weight babies
- Sexually transmitted infection- HIV, gonorrhea.

PREVENTION:

- Drink plenty of water
- Genital hygiene i.e. wears cotton inner wears
- Wear dry and clean underwear
- Sexual partner's genital hygiene
- Clean the anal canal after defecation.
- Yoga and pranayama – It decreases stress and worries or tension.
- A Stress free body can increases resistance to diseases.
- Go on walk
- Improvement of general health [67]

TRIAL DRUG

அகிற் கட்டைச் சூரணம்

“ஒன்றாக இன்னமொரு சூரணங்கேள்
உத்தமனே சந்தனமுமகிற் கட்டை யேலம்
நன்றாகல வங்கப்பட்டைகி ராம்பு சோம்பு
நன்மை யதிமதுரங்கார் போக வித்து
சென்றதோர் வெட்பாலை தேற்றான் வித்து
திறமான அருகம்வேர் சிற்றா முட்டி
பற்றான வேருடனே பன்னி ரெண்டு
பாலகனே வகைக்கரைப லமாய் வாங்கே.

வாங்கியே வெயிலிலுலர்த்திச் சூரணமே செய்து
வண்மையுட னந்திடைக்குகற் கண்டு கூட்டி
தேங்கியே வெருகடிதான் அந்தி சந்தி
திறமான பசுவெண்ணெய்மண்ட லமே கொள்ள
ஓங்கியே ஓடுகிற வெள்ளை தீரும்
உத்தமனே நீரெறிப்புவு டனே தீரும்
பாங்குடனே பத்தியமோ கார மாகா
பரிவான புலத்தியனே பாக மாமே”. (68)

INGREDIENTS

Santhanam, Aghil kattai, elam, Lavangapattai, Kirambu, Soombu, Athimadhuram, Kaarpogi viththu, Vetpaalai arisi, Thaetran kottai, Arugam vaer, Sittramutti, Karkandu.

ACTIONS OF TRIAL DRUGS

S.NO	DRUGS	BOTANICAL NAME	ACTIONS
1	Chandanam	*Santalum album*	Cooling, Diuretic [69]
2	Agil kattai	*Aquilaria agallocha Roxb*	Anti-bacterial activity[70]
3	Elam	*Elettaria cardamomum*	Anti-Infammatory, Anti- microbial Activity[71]
4	Lavangappattai	*Cinnamomum verum*	Anti-microbial Activity, Anti- fungal Activity[72]
5	Kirambu	*Syzygium aromaticum*	Anti-bacterial Activity, Anti-fungal Activity, Anti- Oxidant[73]
6	Sombu	*Pimpinella anisum*	Anti Oxidative property[74]
7	Athi-maduram	*Glycyrrhiza glabra*	Anti-microbial Activity Anti-Inflammatory[75]
8	Karbogi vitthu	*Psoralea corylifolia*	Anti-microbial property[76]
9	Vetpalai arisi	*Wrightia-tinctoria*	Anti-bacterial Activity[77]
10	Thettran vithai	*Strychnos potatorum*	Diuretic Activity[78]
11	Arugam vear	*Cyanodon dactylon*	Diuretic Activity[79]
12	Chitramutti	*Pavonia Zeylanica*	Anti- Inflammatory, Anti- microbial Activity[80]
13	Karkandu	Equal to the amount of chooranam	

Standard Operating Procedure

Source of raw drugs:

The required raw drugs are procured from a well reputed indigenous drug shop. The raw drugs taken for study will be authenticated by the Botanist of Medicinal botany department, Govt. Siddha Medical College, Chennai.

Preparation:

Take each ingredient about 17.5 gm. and made it to dry in the sun light, after that it was ground and powdered. Then equal Quantity of *karkandu* was added and bottled up.

Vehicle : Butter

Dose : 1 gm, twice a day

Duration: 48 Days

INGREDIENTS OF TRIAL DRUG

Aquilaria agallocha

Cinnamomum verum

Cyanodon dactylon

Elettaria cardamomum

Glycyrrhiza glabra

Pavonia zeylanica

Pimpinella anisum

Psoralea corylifolia

Santalum album

Strychnos potatorum

Syzygium aromaticum

Wrightia tinctoria

karkandu

TRIAL MEDICINE

AGHIL KATTAI CHOORANAM

MAERIALS AND METHODS

PROTOCOL

Study Design

A Clinical study on *Vellai noi* was carried out in the Post graduate department of Maruthuvam in Govt. Siddha Medical College attached to Arignar Anna Hospital of Indian Medicine, Chennai – 106 during the period of 2015 – 2017.

The study was approved by Instititional Ethics Committee (IEC) and the approval number is GSMC-CH-ME-4/2015/004. It was registered in Clinical Trials Registry – India (CTRI) and the register number is CTRI/2017/05/008576.

Population and Sample

The Population consists of all the OPD of Arignar Anna Hospital Arumbakkam, Chennai. Sample consists of *Vellai noi* who satisfying the inclusion & exclusion criteria mentioned below.

Sample size

The study is conducted in 20 selected *Vellai noi* patients of female genders between age groups of 18 to 45 years.

Selection Criteria

The patients having following parameters are selected for the study.

- Age :18-45 years
- Whitish/yellowish discharge
- Foul smelling discharge
- Pruritis vulva
- Dysuria
- Cervicitis
- Low backache and Lower abdominal pain
- Positive *Candida*, *Gardnerella vaginalis* infected patients.
- Patient who is willing to cooperate for vaginal swab examination
- Patient who undergo routine blood investigation
- Patient who is willing to participate in trial and signing in consent form.

Exclusion Criteria

- Known case of Diabetes mellitus
- Known case of Sexually transmitted disease (Syphilis, HIV, Gonorrhoea)
- Known case of Nonspecific leucorrhoea (Douches, pessaries, tampons, trauma, drugs, chemicals)
- Pregnancy and Lactation
- Known case of Malignancy in Uterus & Ovary
- *Trichomonas vaginalis* infections.

Proforma

The case sheet proforma for *Vellai noi* was prepared based on Siddha diagnostic methodology with necessary modern techniques.

History taking

For better treatments and results a detailed clinical history was taken regarding present illness, past illness, family history, menstrual history, occupational history, socio economic status, residential area, etc.,

Investigation

All patients were screened by the following investigations. This was carried out regularly before and after treatment.

ROUTINE TESTS AND INVESTIGATIONS

Blood:

TC, DC, ESR, Hb

Blood sugar (Fasting and Post prandial)

Renal function test:

Blood Urea,

Serum Creatinine,

Sonography:

USG –Whole Abdomen

Urine Analysis:

Albumin

Sugar

Deposits

Vaginal smear- Pap smear/wet smear

Drug and dose schedule

Aghil kattai Chooranam – 1 gm, bd after food with butter for 48 days.

RESULTS AND OBSERVATION

The study on *Vellai noi* was carried out in 20 patients in the out-patient department, Pothu Maruthuvam, Govt Siddha Medical College, Chennai-106 attached to Aringnar Anna Hospital 2015-2017 were analysed.

The observations were tabulated regarding the following criteria:

Age distribution

Occupation (Nature of work)

Socio-economic status

Food habits

Marital statuss

Paruvakaalam

Thinai Distribution

Yaakkai Ilakkanam

Duration of illness prior to treatment

Clinical manifestations

Mukkutram- Vatham, Pitham, Kapham

Defects in udal thaathukkal

Envagai thervugal

Naadi

Neikuri

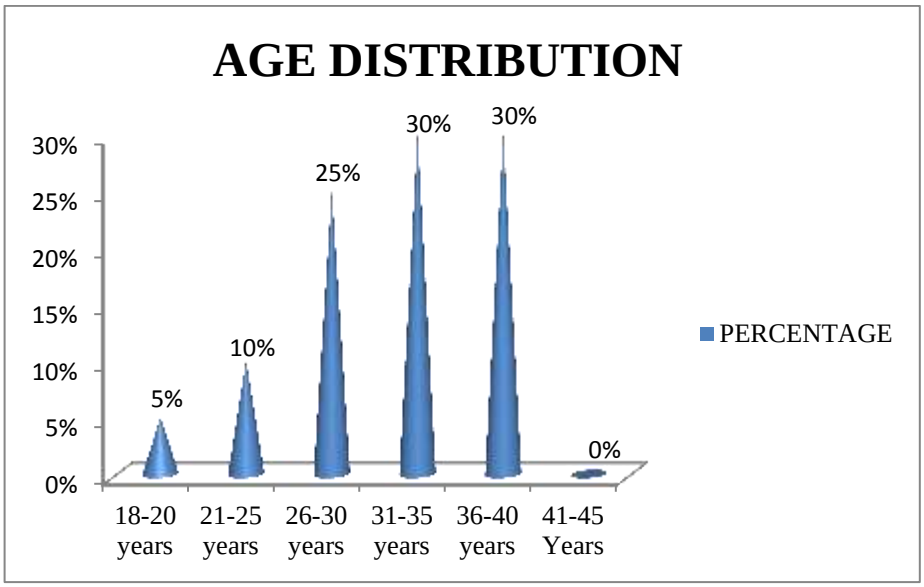
Results after treatment

Grading of Results

Overall Results

AGE DISTRIBUTION

AGE (YEARS)	NO OF CASES/20	PERCENTAGE
18-20 years	1	5%
21-25 years	2	10%
26-30 years	5	25%
31-35 years	6	30%
36-40 years	6	30%
41-45 Years	0	0%

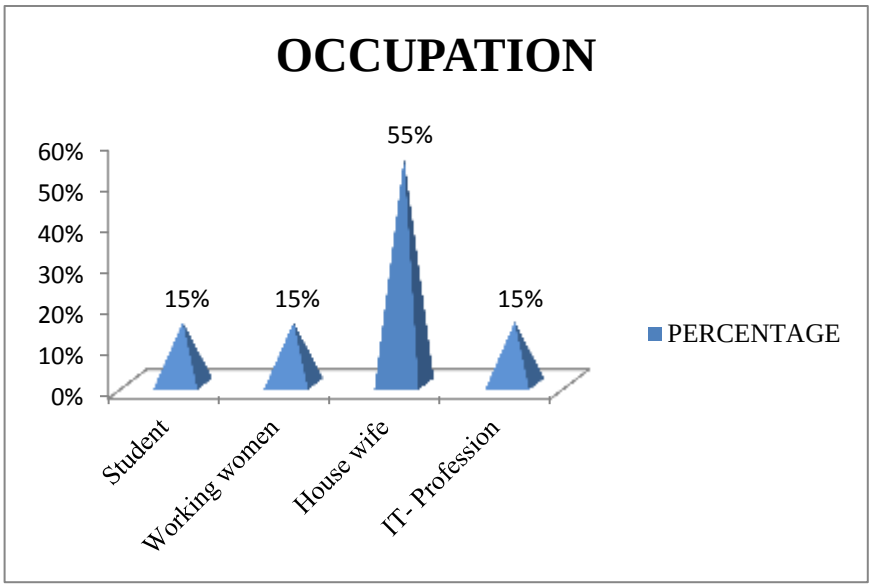


INFERENCES

According to the study, 12 cases (60%) of the total number cases in the age group of 31- 40years.

OCCUPATION (NATURE OF WORK)

WORK	NO.OF CASES /20	PERCENTAGE
Student	3	15%
Working women	3	15%
House wife	11	55%
IT- Profession	3	15%

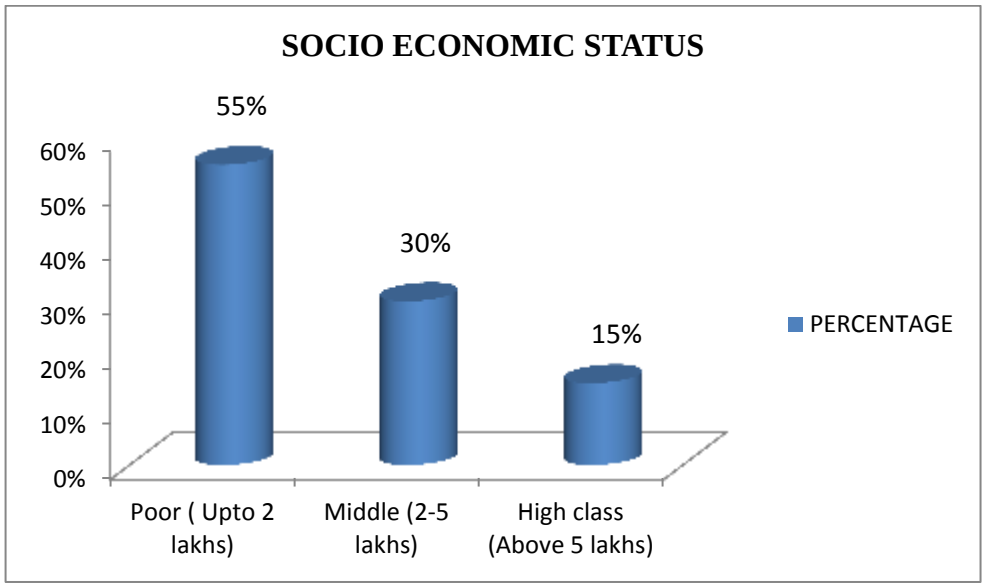


INFERENCE

According to the study, 11 cases were house wife's only.

SOCIO ECONOMIC STATUS

SOCIO ECONOMIC STATUS/ANNUM	NO.OF CASES/20	PERCENTAGE
Poor (Upto 2 lakhs)	11	55%
Middle (2-5 lakhs)	6	30%
High class (Above 5 lakhs)	3	15%

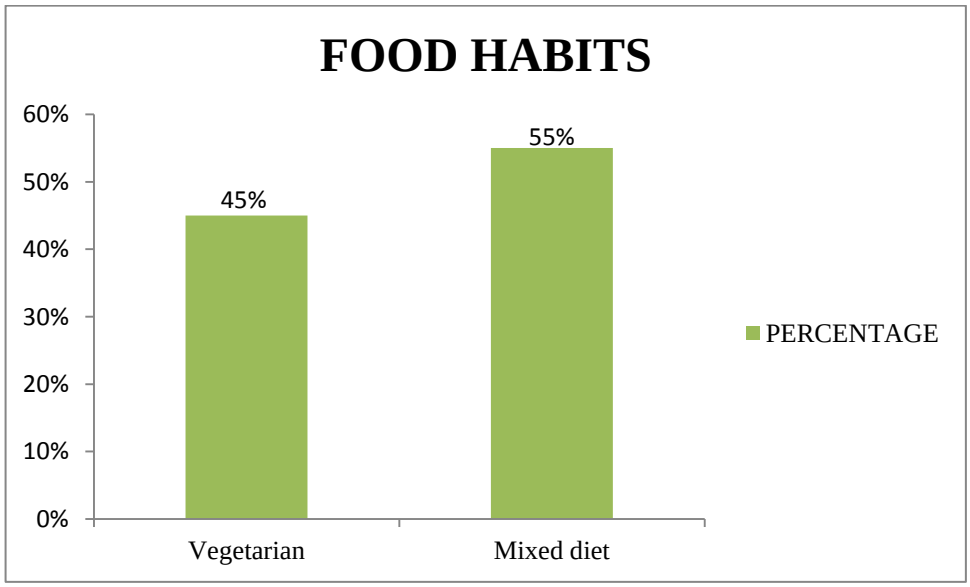


INFERENCE

According to the study nearly 11cases (55%) were from Poor income and 6 cases (30%) from Middle income and 3 cases (15%) from High class income.

FOOD HABITS

DIET	NO.OF CASES/20	PERCENTAGE
Vegetarian	9	45%
Mixed diet	11	55%

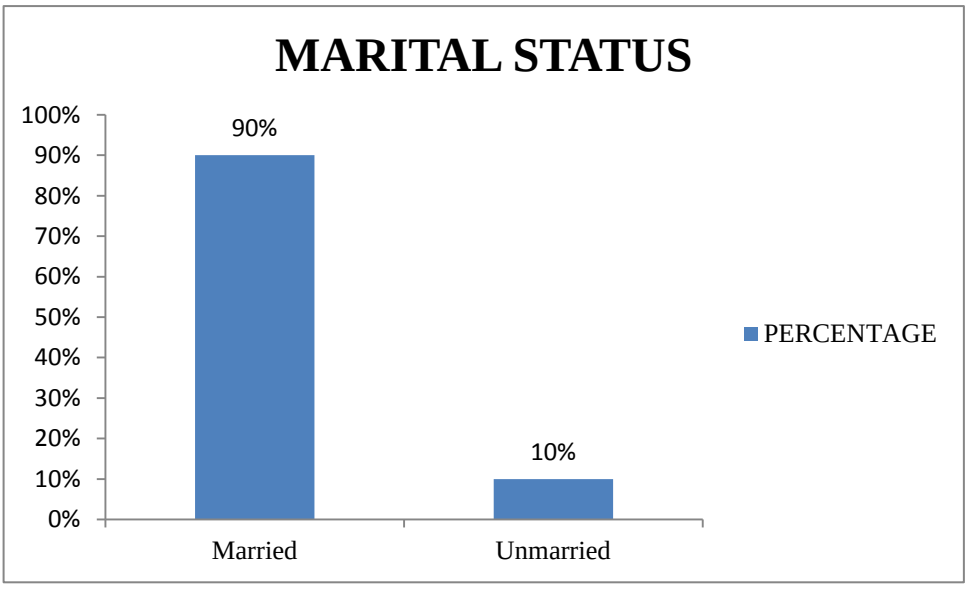


INFERENCE

According to the study, nearly cases (11) had mixed diet and cases (9) had vegetarian diet only.

MARITAL STATUS

MARITAL STATUS	NO.OF CASES/20	PERCENTAGE
Married	18	90%
Unmarried	2	10%

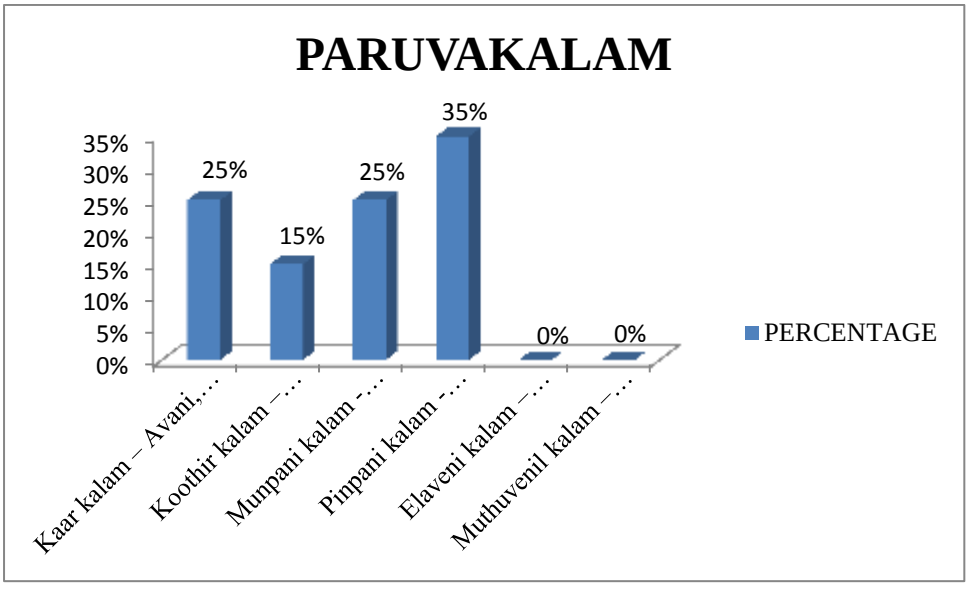


INFERENCE

According to the study, 18 cases are married and 2 unmarried only.

PARUVAKALAM

KAALAM	NO.OF CASES/20	PERCENTAGE
Kaar kalam (Mid Aug – Mid Oct)	5	25%
Koothir kalam (Mid Oct- Mid Dec)	3	15%
Munpani kalam (Mid Dec – Mid Feb)	5	25%
Pinpani kalam (Mid Feb – Mid Apr)	7	35%
Elaveni kalam (Mid Apr- Mid Jun)	0	0%
Muthuvenil kalam (Mid Jun - Mid Aug)	0	0%

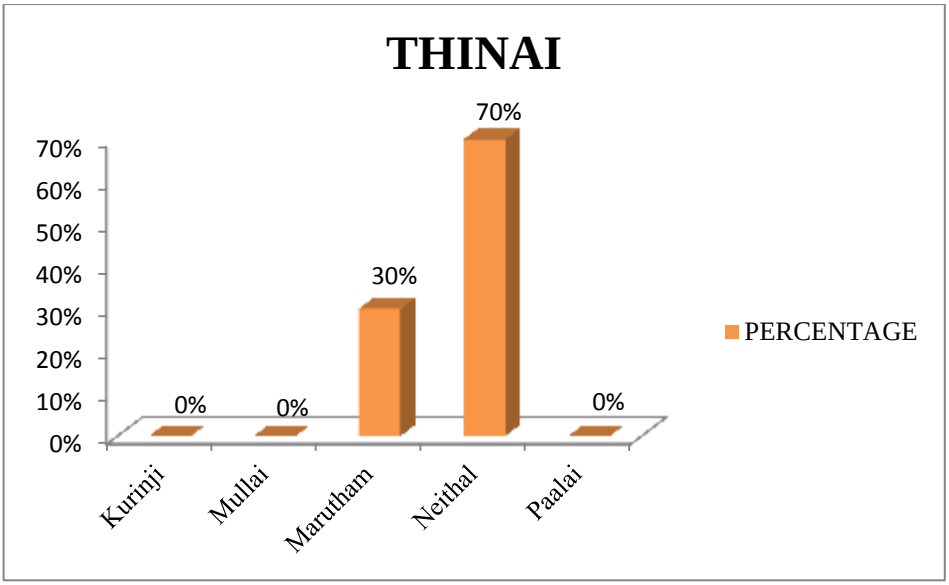


INFERENCE

According to the study 7 cases (35%) in *Pinpani kaalam.*

DISTRIBUTION OF THINAI

THINAI	NO.OF CASES/20	PERCENTAGE
Kurinji	0	0%
Mullai	0	0%
Marutham	6	30%
Neithal	14	70%
Paalai	0	0%

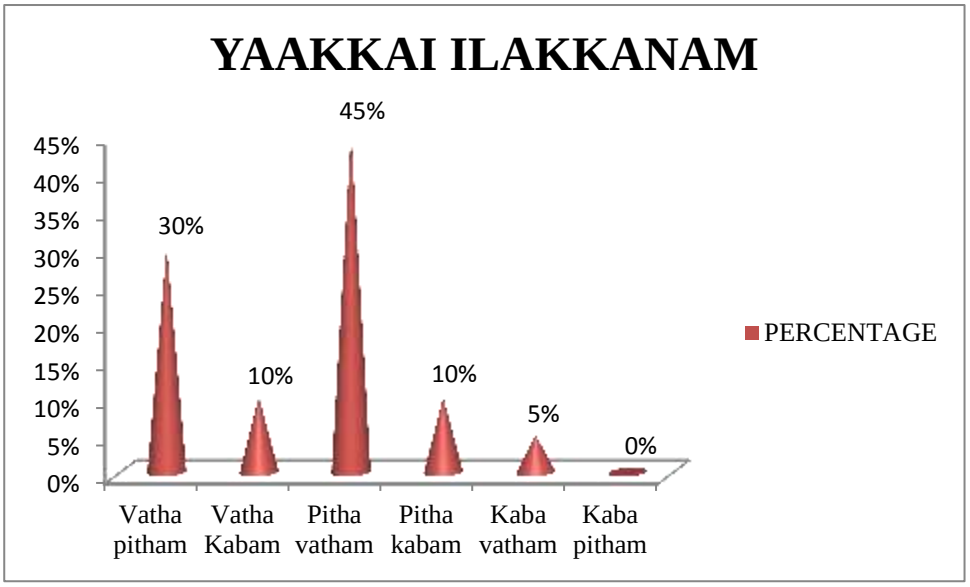


INFERENCE

According to the study, nearly 14 cases (70%) were from NEITHAL THINAI.

YAAKKAI ILAKKANAM

YAKKAI ILAKKANAM	NO OF CASES/20	PERCENTAGE
Vatha pitham	6	30%
Vatha Kabam	2	10%
Pitha vatham	9	45%
Pitha kabam	2	10%
Kaba vatham	1	5%
Kaba pitham	0	0%

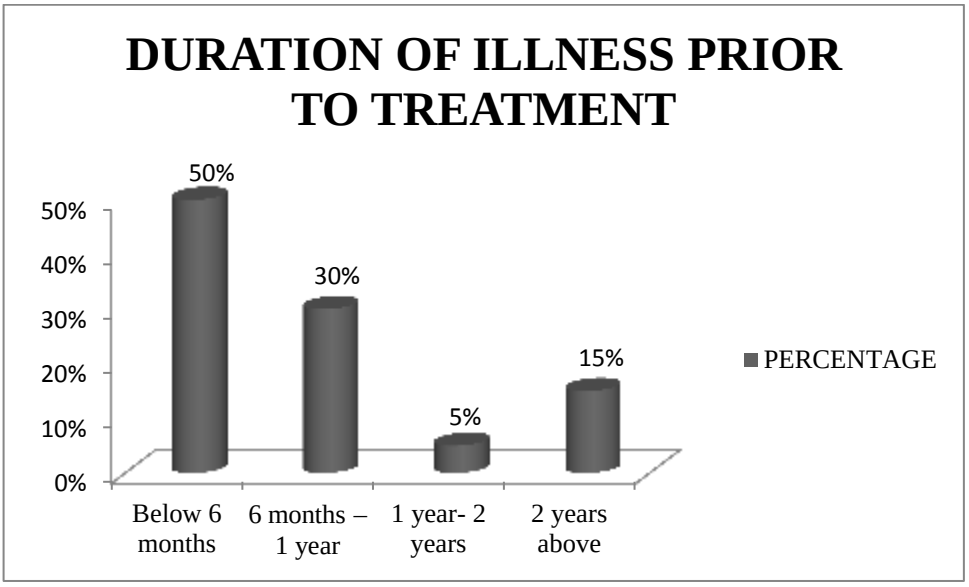


INFERENCE

According to the study, nearly 6 cases (30%)have Vatha pitha yaakkai, 2 cases (10%) have Vatha kabha yaakkai, 9 cases (45%) have Pitha vatha yaakkai, 2 cases (10%) have Pitha kabha yaakkai, 1 case (5%) have kabha vatha yaakkai.

DURATION OF ILLNESS PRIOR TO TREATMENT

DURATION OF ILLNESS	NO OF CASES/20	PERCENTAGE
Below 6 months	10	50%
6 months – 1 year	6	30%
1 year- 2 years	1	5%
2 years above	3	15%

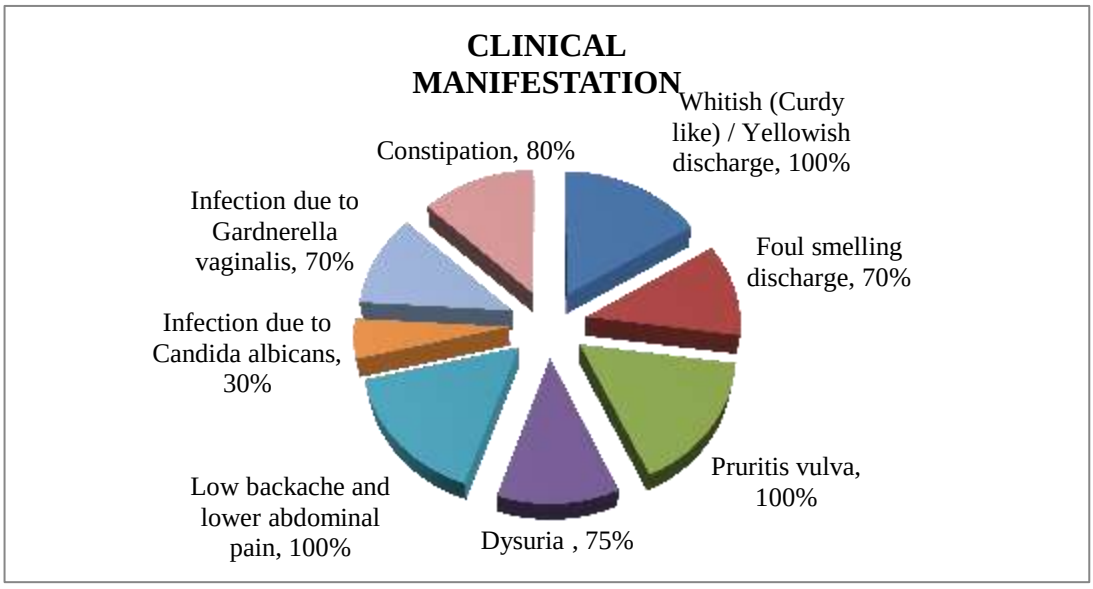


INFERENCES

According to the study, 10 cases (50%) had a duration illness below 6 months.

CLINICAL MANIFESTATION

CLINICAL MANIFESTATION	NO OF CASES/20	PERCENTAGE
Whitish (Curdy like) / Yellowish discharge	20	100%
Foul smelling discharge	14	70%
Pruritis vulva	20	100%
Dysuria	15	75%
Low backache and lower abdominal pain	20	100%
Infection due to Candida albicans	6	30%
Infection due to Gardnerella vaginalis	14	70%
Constipation	16	80%

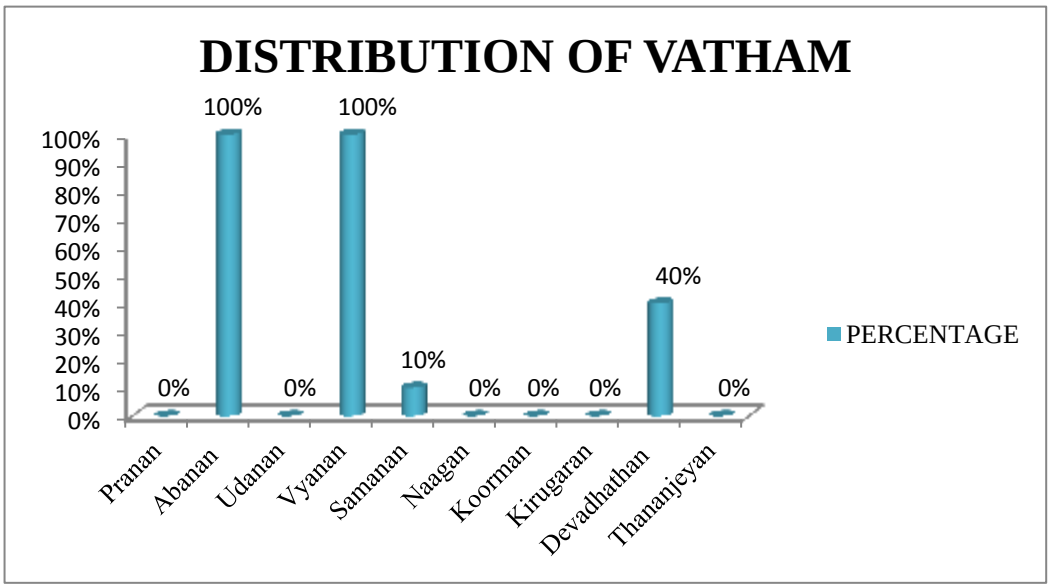


INFERENCES

According to the study, all cases (20) (100%) had Whitish (curdy like)/ Yellowish discharge, pruritis vulva, Low backache and lower abdominal pain.

DISTRIBUTION OF VATHAM

VATHAM	NO.OF CASES/20	PERCENTAGE
Pranan	0	0%
Abanan	20	100%
Udanan	0	0%
Vyanan	20	100%
Samanan	2	10%
Naagan	0	0%
Koorman	0	0%
Kirugaran	0	0%
Devadhathan	8	40%
Thananjeyan	0	0%

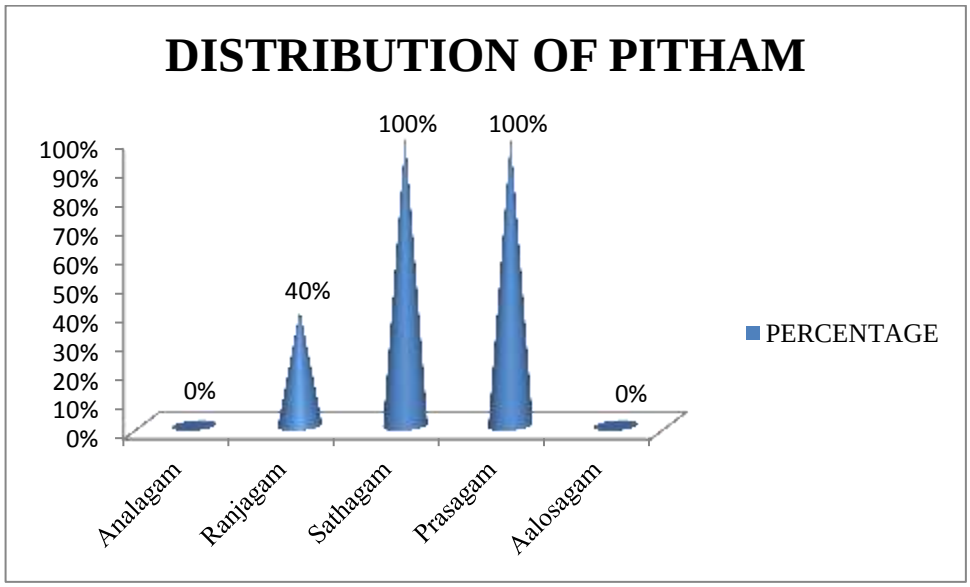


INFERENCE

According to the study, almost all cases (20) (100%) affected by abanan and viyanan.

DISTRIBUTION OF PITHAM

PITHAM	NO. OF CASES/20	PERCENTAGE
Analagam	0	0%
Ranjagam	8	40%
Sathagam	20	100%
Prasagam	20	100%
Aalosagam	0	0%

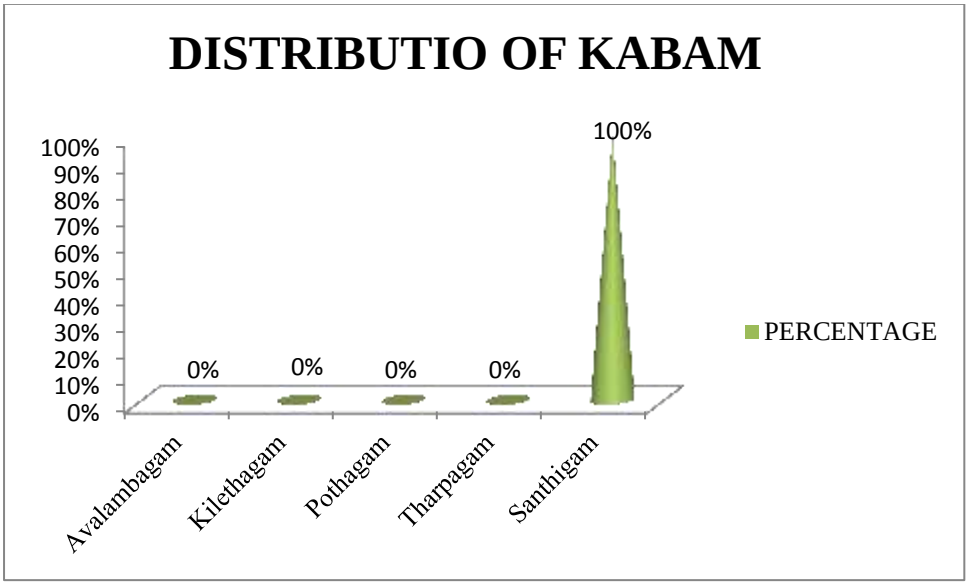


INFERENCE

According to the study, almost all cases (20) (100%) affected by Saathaga and Prasaga Pitham.

DISTRIBUTION OF KABAM

KABAM	NO. OF CASES/20	PERCENTAGE
Avalambagam	0	0%
Kilethagam	0	0%
Pothagam	0	0%
Tharpagam	0	0%
Santhigam	20	100%

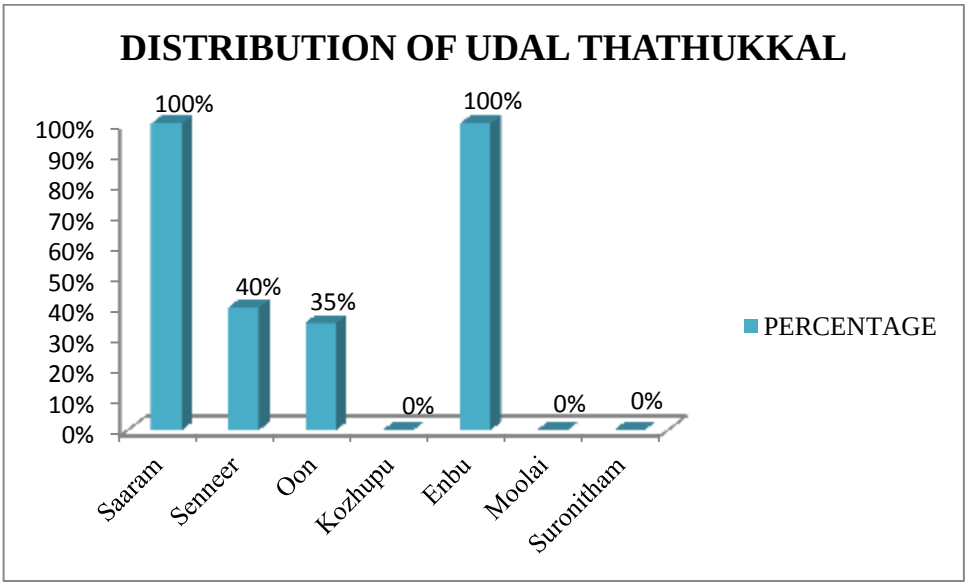


INFERENCE

According to the study, all cases (20) (100%) affected by Santhigam.

DISTRIBUTION OF UDAL THATHUKKAL

THATHUKKAL	NO.OF CASES/20	PERCENTAGE
Saaram	20	100%
Senneer	8	40%
Oon	7	35%
Kozhupu	0	0%
Enbu	20	100%
Moolai	0	0%
Suronitham	0	0%

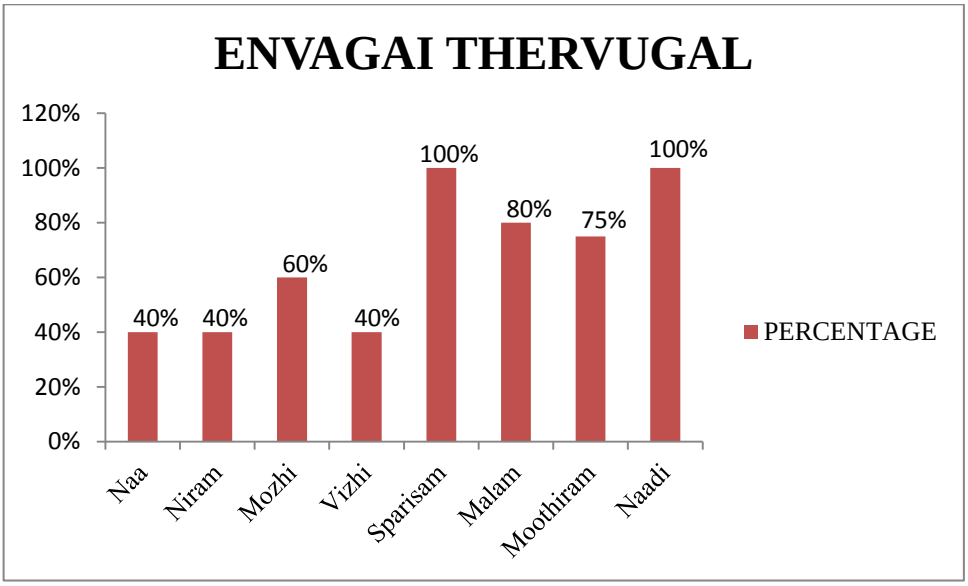


INFERENCE

According to the study, all cases 20(100%) affected by Saaram, Enbu.

ENVAGAI THERVUGAL

THERVUGAL	NO.OF CASES/20	PERCENTAGE
Naa	8	40%
Niram	8	40%
Mozhi	12	60%
Vizhi	8	40%
Sparisam	20	100%
Malam	16	80%
Moothiram	15	75%
Naadi	20	100%

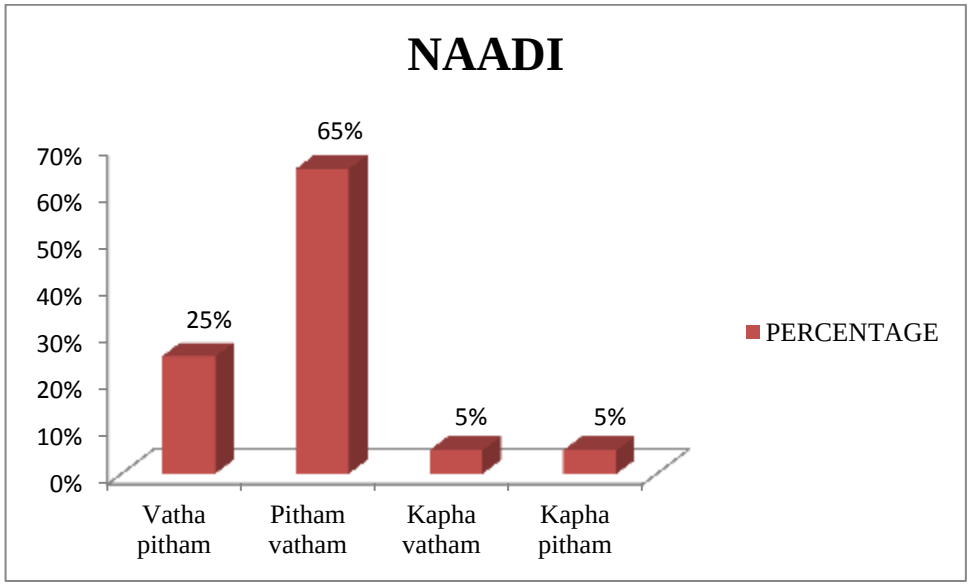


INFERENCE

According to the study Envagai thervugal affected in the following no of cases, Naa- 8 cases (40%), Niram – 8 cases (40%), Mozhi -12 cases (60%), Vizhi- 8 cases (40%), Sparisam-20 cases (100%), Malam- 16 cases (80%), Moothiram – 15 cases (75%), Naadi- 20 cases (100%).

NAADI

NAADI	NO. OF CASES/20	PERCENTAGE
Vatha pitham	5	25%
Pitham vatham	13	65%
Kapha vatham	1	5%
Kapha pitham	1	5%

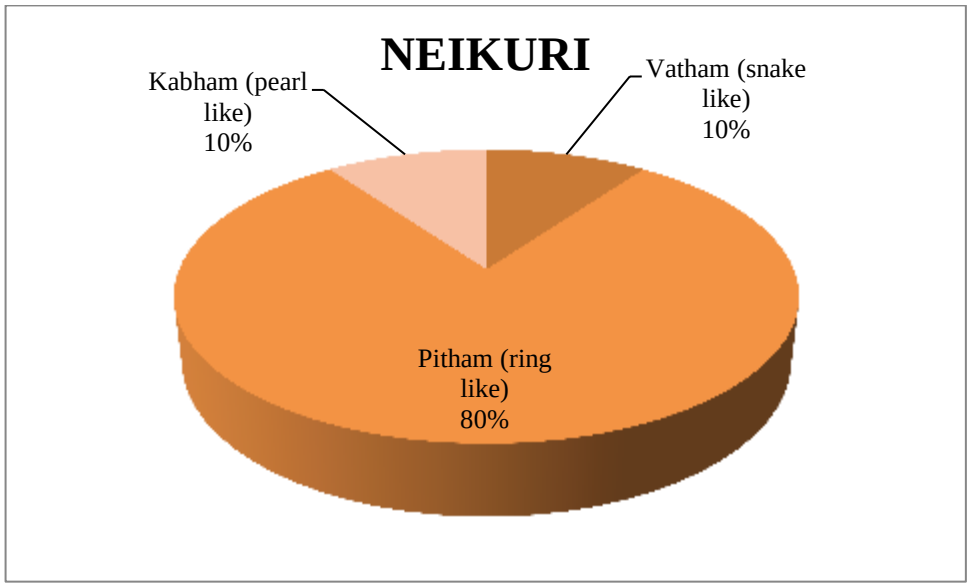


INFERENCE

According to the study mostly affected Naadi is Pitha vatham (65%)

NEIKURI

NEIKURI	NO. OF CASES/20	PERCENTAGE
Vatham (snake like)	2	10%
Pitham (ring like)	16	80%
Kabham (pearl like)	2	10%



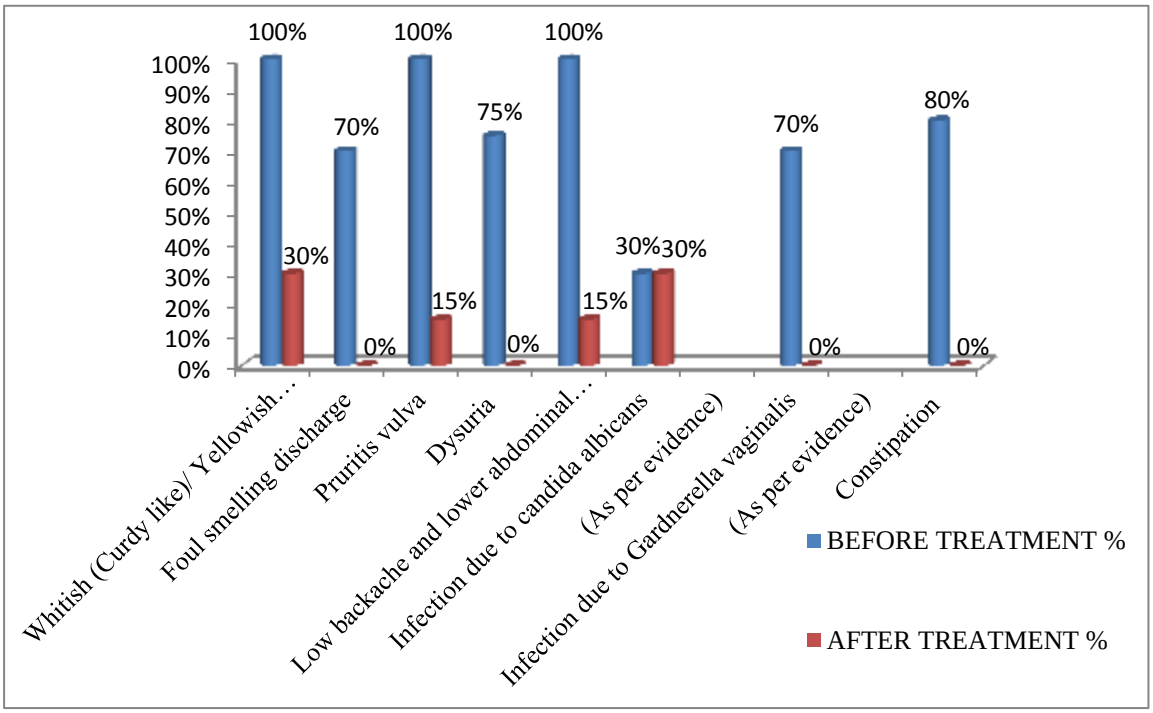
INFERENCE

According to the study, nearly 16 cases (80%) had Ring like spread by dropping gingely oil in urine.

RESULT AFTER TREATMENT - CLINICAL PROGNOSIS

CLINICAL MANIFESTATION	BEFORE TREATMENT		AFTER TREATMENT		IMPROVEMENT	
	NO OF CASES	PERCENTAGE	NO OF CASES	PERCENTAGE	NO OF CASES	PERCENTAE
Whitish (Curdy like)/ Yellowish discharge	20	100%	7	30%	13	65%
Foul smelling discharge	14	70%	0	0%	14	100%
Pruritis vulva	20	100%	3	15%	17	85%
Dysuria	15	75%	0	0%	15	100%
Low backache and lower abdominal pain	20	100%	3	15%	17	85%
Infection due to *Candida albicans* (As per evidence)	6	30%	6	30%	0	0%
Infection due to *Gardnerella vaginalis* (As per evidence)	14	70%	0	0%	14	100%
Constipation	16	80%	0	0%	16	100%

RESULT AFTER TREATMENT- CLINICAL PROGNOSIS

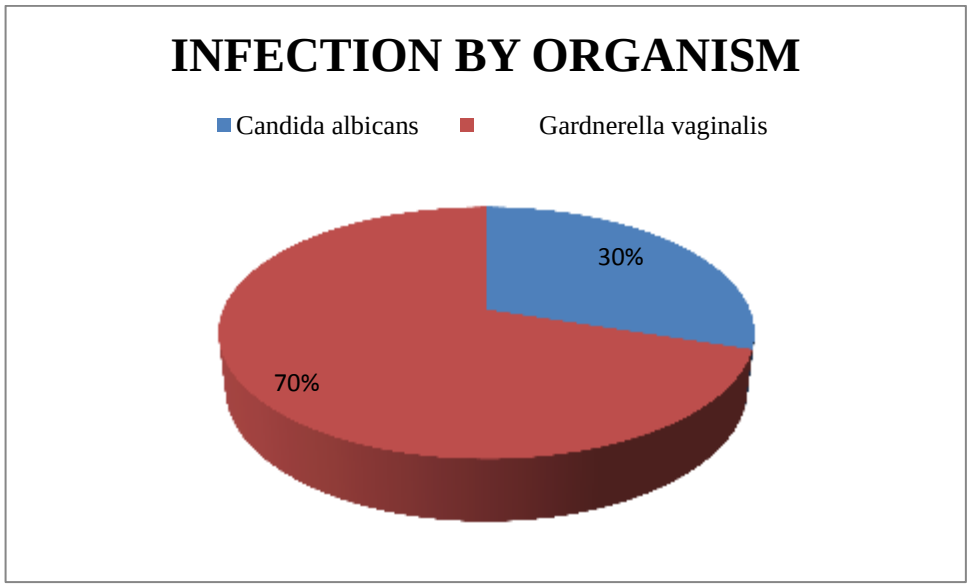


INFERENCE

According to the study, the patients after treated with Siddha herbal formulation *Aghil kattai chooranam*, the symptoms such as whitish discharge, foul smelling discharge, pruritis vulva, dysuria, low backache and lower abdominal pain, infection due to *candida albicans*, infection due to *garenerella vaginalis*, constipation was reduced greatly and the health was well improved as 65%, 100%, 85%, 100%, 85%, 0%, 100%, 100% respectively.

INFECTION BY ORGANISM

ORGANISM	NO. OF CASES/20	PERCENTAGE %
Candida albicans	6	30%
Gardnerella vaginalis	14	70%

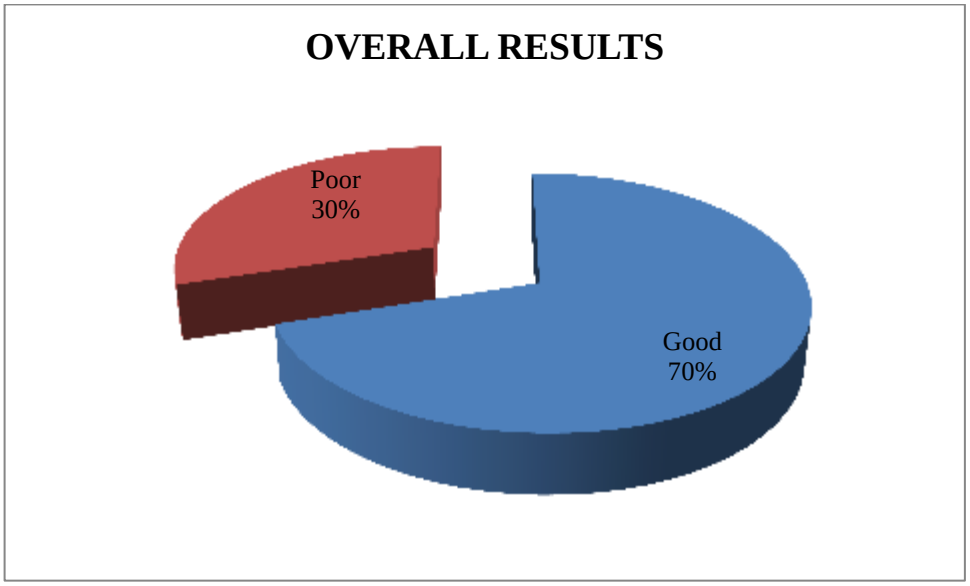


INFERENCE

Out of 20 patients, 14 patients (70%) were infected by *Gardnerella vaginalis*, 6 patients (30%) were infected by *Candida albicans.*

OVERALL RESULT

RESULT	NO. OF CASES/20	PERCENTAGE
Good	14	70%
Poor	6	30%



INFERENCE

Out of 20 cases, 14 cases (70%) had good results, 6 cases (30%) had Poor results.

CASE SUMMARY OF OUT PATIENTS

S. No	OP No	AGE/ SEX	DATE OF 1st VISIT	DATE OF LAST VISIT	NO. OF DAYS TREATED
1	1338	30 F	19-Sep-16	5- Nov-16	48 days
2	2056	33 F	21-Sep-16	5-Nov-16	46 days
3	3489	39 F	26-Sep- 16	7-Nov-16	43 days
4	9693	30 F	30-Sep-16	13-Nov-16	45 days
5	4703	32 F	30-Sep-16	13-Nov-16	45 days
6	8962	18 F	17-Oct-16	30-Nov-16	45 days
7	125	36 F	21-Oct-16	8-Dec-16	48 days
8	4974	37 F	10-Nov-16	21-Dec-16	41 days
9	185	35 F	10-Jan-17	20-Feb-17	41 days
10	2770	35 F	23-Jan-17	27-Feb-17	48 days
11	6905	27 F	7-Feb-17	29-Mar-17	51 days
12	9920	28 F	8-Feb-17	27-Mar-17	48 days
13	8527	33 F	13-Feb-17	31-Mar-17	47 days
14	8390	29 F	13-Feb-17	30-Mar-17	46 days
15	8955	24 F	15-Feb-17	2-Apr-17	47 days
16	9076	40 F	15-Feb-17	26-Mar-17	40 days
17	9236	33 F	16-Feb-17	28-Mar-17	41 days
18	235	39 F	20-Feb-17	4-Apr-17	44 days
19	4383	32 F	6-Mar-17	19-Apr-17	45 days
20	7108	23 F	15-Mar-17	23-Apr-17	45 days

HAEMATOLOGICAL REPORT

S. NO	OP NO	AGE/ SEX	BT	AT	BT			AT			BT		AT		BT	AT
			TC	TC	DC			DC			ESR		ESR		Hb	Hb
					P	L	E	P	L	E	½ hr	1 hr	½ hr	1 hr		
1	1338	30 F	4800	5100	54	39	7	52	42	6	5	16	4	12	10.0	11.0
2	2056	33 F	5200	5800	55	37	8	54	39	7	10	25	8	22	12.7	12.9
3	3489	39 F	10300	9100	59	35	6	58	36	6	35	72	26	60	13.0	12.0
4	9693	30 F	8400	8500	52	42	6	52	41	7	8	15	7	12	8.8	9.2
5	4703	32 F	9200	9000	64	30	6	60	34	6	8	23	7	18	8.8	9.9
6	8962	18 F	8500	9100	66	28	6	65	29	6	16	29	10	18	9.2	10.8
7	125	36 F	10700	8500	72	23	5	69	27	4	12	25	9	22	10.6	11.0
8	4974	37 F	6700	8100	63	32	5	58	37	5	15	32	8	28	12.6	12.4
9	185	35 F	8700	7700	71	22	7	68	26	6	14	33	12	26	8.0	9.0
10	2770	35 F	10500	9400	65	31	4	65	32	3	35	58	26	46	12.2	12.0
11	6905	27 F	6800	8200	46	45	9	46	48	6	5	12	3	8	10.6	10.4
12	9920	28 F	10500	9800	71	23	6	69	23	8	12	25	10	18	13.3	13.2
13	8527	33 F	6800	7200	53	39	8	51	42	7	5	17	3	14	12.3	13.0
14	8390	29 F	8300	9200	66	27	7	63	32	5	12	21	8	18	10.5	11.0
15	8955	24 F	4700	5100	49	43	8	48	45	7	3	5	3	4	12.3	12.3
16	9076	40 F	7900	6500	66	26	8	64	28	8	30	55	26	40	12.9	12.4
17	9236	33 F	9600	8400	72	25	3	69	28	3	18	35	11	28	7.6	9.2
18	235	39 F	8500	8400	58	33	9	56	36	8	15	28	12	22	9.6	10.8
19	4383	32 F	7200	7300	65	30	5	64	31	5	12	22	8	10	10.9	11.4
20	7108	23 F	10300	9300	63	29	8	62	30	8	14	22	12	20	8.5	10.0

URINE ANALYSIS

S.NO	OP. NO	URINE ANALYSIS						BLOOD UREA		SERUM CRETININE	
		BEFORE TREATMENT			AFTER TREATMENT			BT	AT	BT	AT
		Alb	Sug	Dep	Alb	Sug	Dep				
1	1338	-	-	0-3	-	-	-	40	34	1.2	1.0
2	2056	-	-	0-2	-	-	0-2	39	36	1.0	1.2
3	3489	-	-	-	-	-	-	36	38	0.8	0.9
4	9693	-	-	1-3	-	-	0-2	37	32	1.0	1.2
5	4703	-	-	0-3	-	-	-	29	21	0.5	0.7
6	8962	-	-	-	-	-	-	35	35	0.9	1.1
7	125	-	-	0-3	-	-	0-2	34	34	1.3	1.2
8	4974	-	-	-	-	-	0-3	36	37	0.6	0.5
9	185	-	-	1-3	-	-	-	37	39	0.4	0.6
10	2770	-	-	-	-	-	-	30	31	1.2	1.2
11	6905	-	-	0-3	-	-	-	39	30	1.0	1.1
12	9920	-	-	0-3	-	-	1-3	37	38	0.4	0.3
13	8527	-	-	-	-	-	-	33	30	0.6	0.4
14	8390	-	-	-	-	-	-	30	29	1.6	1.2
15	8955	-	-	0-3	-	-	1-3	35	35	0.7	0.8
16	9076	-	-	-	-	-	-	29	28	1.1	1.0
17	9236	-	-	-	-	-	-	34	34	0.8	0.7
18	235	-	-	0-3	-	-	-	32	29	0.6	0.6
19	4383	-	-	1-3	-	-	1-3	39	34	0.2	0.3
20	7108	-	-	-	-	-	-	38	40	0.6	1.0

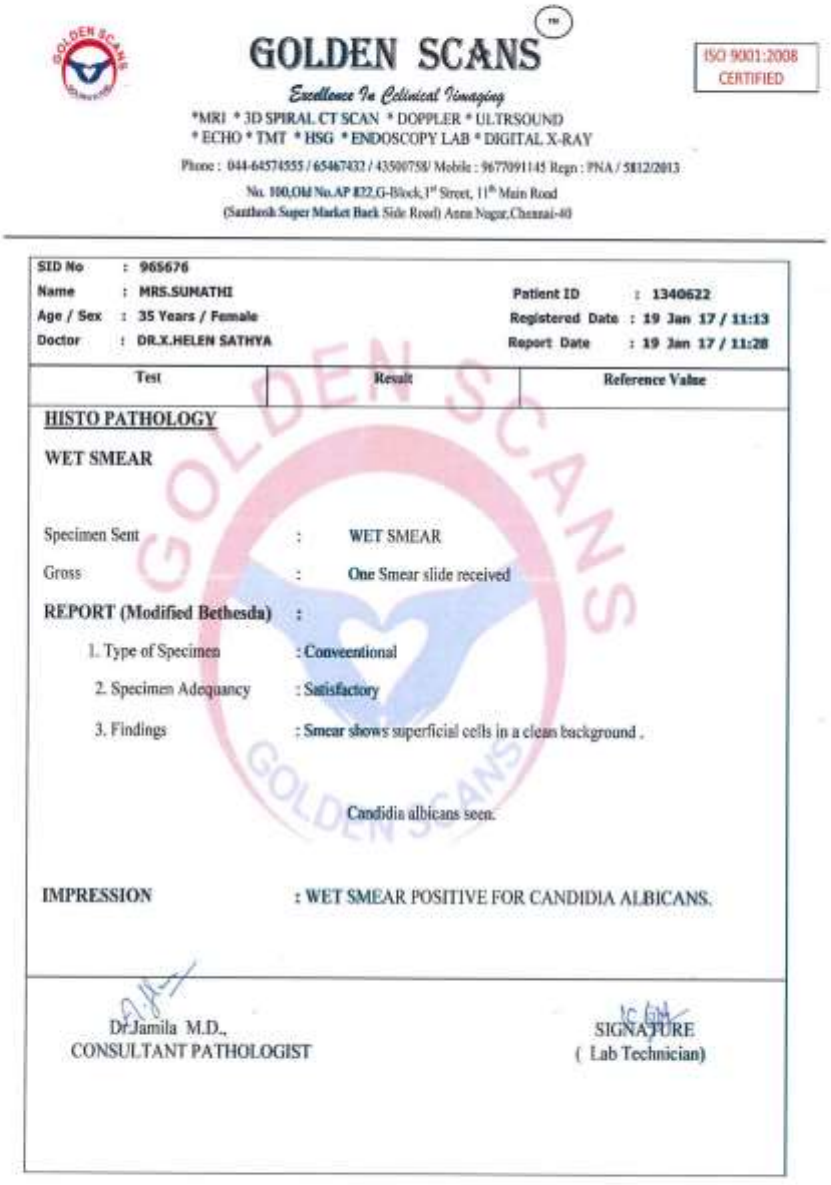
LABORATORY INVESTIGATION – VAGINAL SMEAR

S. NO	OP. NO	AGE/ SEX	VAGINAL SMEAR			
			BEFORE TREATMENT		AFTER TREATMENT	
			GARDNERELLA VAGINALIS	CANDIDA ALBICANS	GARDNERELLA VAGINALIS	CANDIDA ALBICANS
1	1338	30 F	-	+		+
2	2056	33 F	+	-	-	
3	3489	39 F	+	-	-	
4	9693	30 F	+	-	-	
5	4703	32 F	+	-	-	
6	8962	18 F	+	-	-	
7	125	36 F	+	-	-	
8	4974	37 F	-	+		+
9	185	35 F	+	-	-	
10	2770	35 F	-	+		+
11	6905	27 F	+	-	-	
12	9920	28 F	+	-	-	
13	8527	33 F	+	-	-	
14	8390	29 F	-	+		+
15	8955	24 F	+	-	-	
16	9076	40 F	+	-	-	
17	9236	33 F	-	+		+
18	235	39 F	-	+		+
19	4383	32 F	+	-	-	
20	7108	23 F	+	-	-	

LABORATORY INVESTICATION - BLOOD SUGAR REPORT

S. NO	OP NO	AGE/ SEX	BLOOD SUGAR					
			BEFORE TREATMENT			AFTER TREATMENT		
			F	PP	R	F	PP	R
1	1338	30 F	68	72	-	68	74	-
2	2056	33 F	-	-	97	-	-	96
3	3489	39 F	80	114	-	78	115	-
4	9693	30 F	92	112	-	93	113	-
5	4703	32 F	86	124	-	87	125	-
6	8962	18 F	74	99	-	73	99	-
7	125	36 F	97	-	-	97	-	-
8	4974	37 F	62	98	-	61	99	-
9	185	35 F	93	-	-	92	-	-
10	2770	35 F	-	-	90	-	-	92
11	6905	27 F	-	-	85	-	-	85
12	9920	28 F	-	-	76	-	-	78
13	8527	33 F	-	-	80	-	-	84
14	8390	29 F	-	-	70	-	-	69
15	8955	24 F	98	-	-	102	-	-
16	9076	40 F	82	105	-	76	102	-
17	9236	33 F	86	102	-	80	94	-
18	235	39 F	77	96	-	81	92	-
19	4383	32 F	77	101	-	78	98	-
20	7108	23 F	68	118	-	72	101	-

BEFORE TREATMENT



GOLDEN SCANS

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ISO 9001:2008 CERTIFIED

*MRI * 3D SPIRAL CT SCAN * DOPPLER * ULTRSOUND
* ECHO * TMT * HSG * ENDOSCOPY LAB * DIGITAL X-RAY

Phone : 044-64574555 / 65467432 / 43500758/ Mobile : 9677091145 Regn : PNA / 5812/2013

No. 100,Old No.AP 822,G-Block,1st Street, 11th Main Road
(Santhosh Super Market Back Side Road) Anna Nagar,Chennai-40

SID No	: 965676		
Name	: MRS.SUMATHI	Patient ID	: 1340622
Age / Sex	: 35 Years / Female	Registered Date	: 19 Jan 17 / 11:13
Doctor	: DR.X.HELEN SATHYA	Report Date	: 19 Jan 17 / 11:28

Test	Result	Reference Value

HISTO PATHOLOGY

WET SMEAR

Specimen Sent : WET SMEAR

Gross : One Smear slide received

REPORT (Modified Bethesda) :

1. Type of Specimen : Conveentional
2. Specimen Adequancy : Satisfactory
3. Findings : Smear shows superficial cells in a clean background .

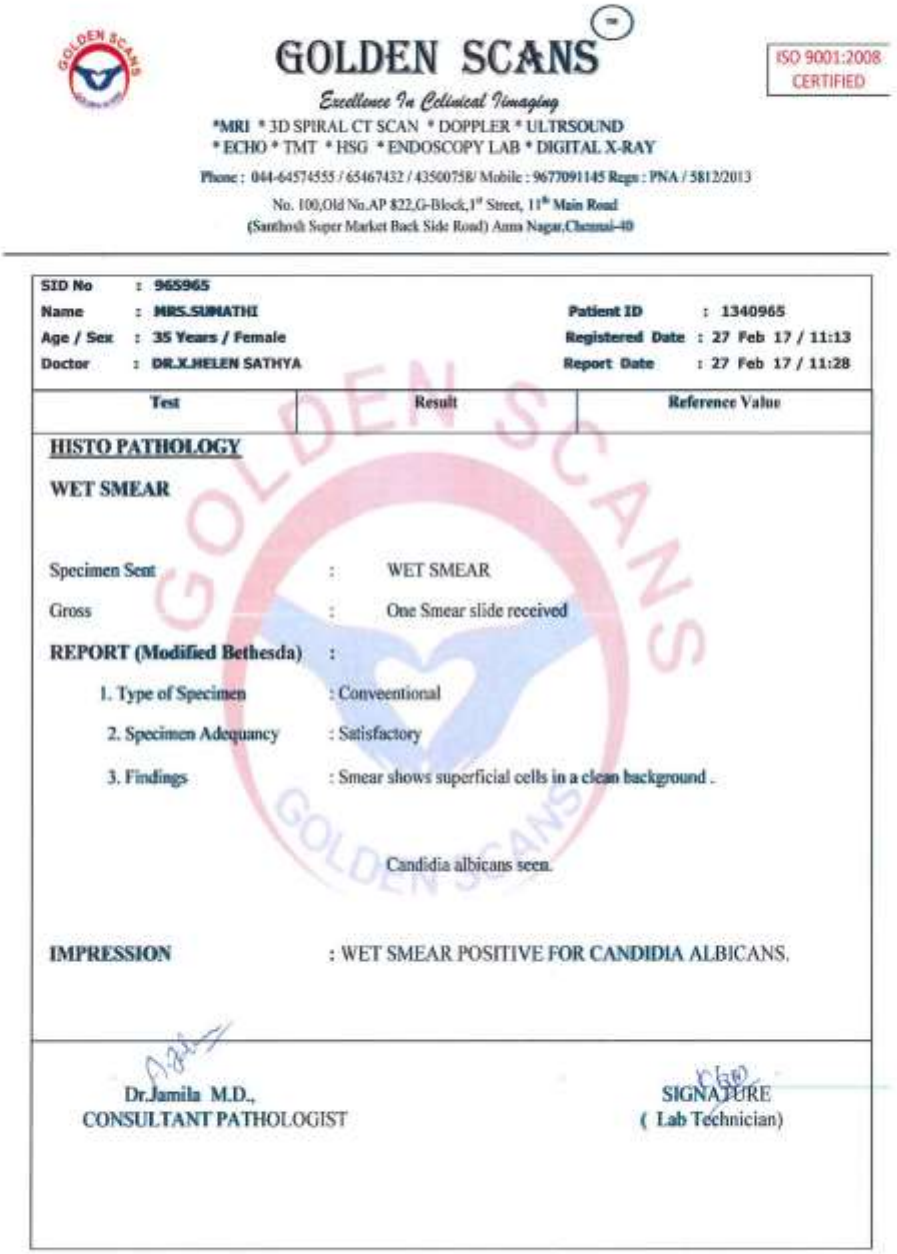
Candidia albicans seen.

IMPRESSION : WET SMEAR POSITIVE FOR CANDIDIA ALBICANS.

Dr.Jamila M.D.,
CONSULTANT PATHOLOGIST

SIGNATURE
(Lab Technician)

AFTER TREATMENT



GOLDEN SCANS

Excellence In Clinical Imaging

ISO 9001:2008 CERTIFIED

*MRI * 3D SPIRAL CT SCAN * DOPPLER * ULTRSOUND
* ECHO * TMT * HSG * ENDOSCOPY LAB * DIGITAL X-RAY

Phone : 044-64574555 / 65467432 / 43500758/ Mobile : 9677091145 Regn : PNA / 5812/2013

No. 100,Old No.AP 822,G-Block,1st Street, 11th Main Road
(Santhosh Super Market Back Side Road) Anna Nagar,Chennai-40

SID No	: 965965		
Name	: MRS.SUMATHI	Patient ID	: 1340965
Age / Sex	: 35 Years / Female	Registered Date	: 27 Feb 17 / 11:13
Doctor	: DR.X.HELEN SATHYA	Report Date	: 27 Feb 17 / 11:28

Test	Result	Reference Value

HISTO PATHOLOGY

WET SMEAR

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3. Findings : Smear shows superficial cells in a clean background .

Candidia albicans seen.

IMPRESSION : WET SMEAR POSITIVE FOR CANDIDIA ALBICANS.

Dr.Jamila M.D.,
CONSULTANT PATHOLOGIST

SIGNATURE
(Lab Technician)

BEFORE TREATMENT

CHENNAI (THYROID) CLINICAL LABORATORY
(Lab, ECG, Xray, EEG)
AMINJIKARAI : #.537/310, Poonamallee High Road, Aminjikarai, Chennai-600 029.
(Opp.Market Signal) Cell : 98415 86827. Ph : 044-26642827

Pt Name : Mrs.Parveen Fathima. Age : 22 yrs

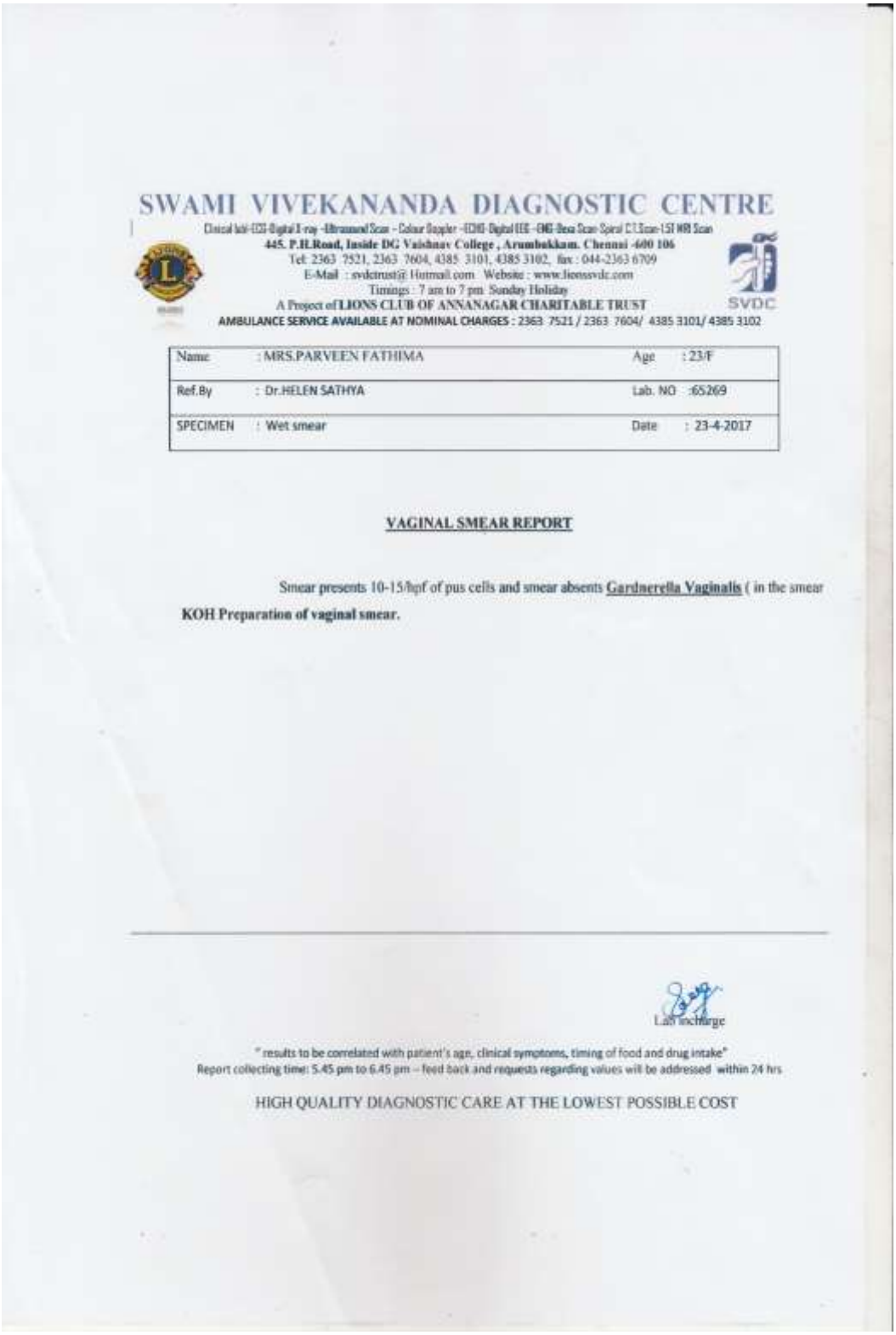
Ref By Dr : Helan Sathiya MD(S). Date: 14/12/2016

VAGINAL SMEAR REPORT

Smear presents 10-15/hpf of pus cells and smear presents Gardnerella vaginalis/ in the smear KOH Prepration of vaginal smear negative candida albicans

H.Syed Aminjikarai
B.sc.DMLT.,BMSP.

AFTER TREATMENT



SWAMI VIVEKANANDA DIAGNOSTIC CENTRE

Clinical lab -ECG -Digital X-ray -Ultrasound Scan - Colour Doppler -ECHO -Digital ECG -OPG -Bone Scan Spiral C.T.Scan-1.5T MRI Scan

445, P.H.Road, Inside DG Vaishnav College , Arumbakkam. Chennai -600 106

Tel: 2363 7521, 2363 7604, 4385 3101, 4385 3102, fax : 044-2363 6709

E-Mail : svdctrust@ Hotmail.com Website : www.lionssvdc.com

Timings : 7 am to 7 pm Sunday Holiday

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SVDC

AMBULANCE SERVICE AVAILABLE AT NOMINAL CHARGES : 2363 7521 / 2363 7604/ 4385 3101/ 4385 3102

Name	: MRS.PARVEEN FATHIMA	Age	: 23/F
Ref.By	: Dr.HELEN SATHYA	Lab. NO	:65269
SPECIMEN	: Wet smear	Date	: 23-4-2017

VAGINAL SMEAR REPORT

Smear presents 10-15/hpf of pus cells and smear absents Gardnerella Vaginalis (in the smear

KOH Preparation of vaginal smear.

Lab incharge

" results to be correlated with patient's age, clinical symptoms, timing of food and drug intake"

Report collecting time: 5.45 pm to 6.45 pm -- feed back and requests regarding values will be addressed within 24 hrs

HIGH QUALITY DIAGNOSTIC CARE AT THE LOWEST POSSIBLE COST

DISCUSSION

VELLAI NOI which has been compared with the modern clinical entity **LEUCORRHOEA**. Leucorrhoea are the most common gynaecological condition to be referred to hospitals. Vulvovaginal *Candidiasis* affects about 75% of women at some time during their reproductive life, with 40 - 50% having two or more episodes. Bacterial vaginosis is also very common, but as 50% of cases of bacterial vaginosis are asymptomatic, the true prevalence of this condition in the community is uncertain.

Many authors have documented vaginal discharge as one of the commonest symptom of genital tract disease reported by women in India.

Most common cause Leucorrhoea are which may be specific due to infections caused by sexually transmitted diseases (STD) such as *gonorrhea*, protozoal organisms such as *Trichomonas vaginalis*, and fungi such as *Candida albicans*; or non – specific due to infection through mixed organisms such as *Strepto coccus, Staphylococcus*, *Hemophilus vaginalis*, *E. coli* or anerobes. This latter condition is seen in women using pessaries, tampons and other foreign bodies and chemicals, and in postmenopausal women.

The definitive treatment is appropriate to the cause for Leucorrhoea. Hence with the help of the trial medicine from the Siddha system of medicine, results and observations are noted for this study.

20 patients with *VELLAI NOI* were selected. The patients were examined based on Siddha and as well as modern aspects. All the necessary investigations were made for all patients during the study. All the patients were administered with the *Aghil kattai chooranam.*

The clinical improvement of the patients was completely observed and efficacy of the *Aghil kattai chooranam* has been studied in this study. Results obtained were discussed below for better conclusion.

Drug Authentication

I have got a drug authentication of raw drug herbal sample collected from raw drug store like *Thettran, Chitrathai, Arugam pul, Elam, Kirambu, Sombu, Athimathuram, Elavangapattai, Karpoga arisi, Vetpalai, Santhanam, Akil, karkandu* and its organoleptic characters, Microscopic and Macroscopic examination was

conducted and authenticated by Botanist (Dept of Medicinal botany), Govt. Siddha medical college, Arumbakkam, Chennai-106.

Physico chemical Analysis

Loss of Drying (at 105^0C) was 7.54%, The total value of *Aghil kattai chooranam* was 5.0%, The water soluble ash value was 2.025%, The Acid insoluble ash value was 0.678%, The water soluble extractive value was 20.95%, The Alcohol soluble extractive value was 18.06%, The pH Value was 6.48.

TOXICOLOGICAL STUDY:

I got IAEC Approval from Sathyabama University, Chennai, Tamil nadu, India for pre-clinical studies. IAEC Approval No: SU/CLATR/IAEC/IV/016/2016.

Acute Toxicity

Acute toxicity study of the trial drug *Aghil kattai chooranam* was carried out as per OECD guideline - 423 (Organization for Economic co-operation and Development). The acute toxicity study of my trial drug was studied and the drug was proved safer for long term administration, as it did not exibit any significant toxicity at 2000mg/kg body weight.

Sub-acute Toxicity

Sub-acute toxicity study as per OECD guideline of – 407 under the dosage of trial drug 200mg/kg (Low dose), 400 mg/kg (High dose) it did not exhibit any significant.

Histo pathology:

At the end of toxicity studies the animal was sacrificed and they were subjected to haematological parameters (TC, DC & Hb) chemical parameters (LFT, RFT) and histopathology of vital organs like Liver, Kidney, Spleen, Lungs was carried out. The studied did not exhibit the evidence of remarkable pathological lesions in the tissues.

PHARMACOLOGICAL STUDY:

- The culture study of *Aghil kattai chooranam* showed significant Antibacterial activity. And it was done by disk diffusion method.
- *Aghil kattai chooranam* has no positive results in Antifungal activity.

Biochemical analysis

In *Aghil kattai chooranam* contains, basic radicals like iron, calcium, reducing sugar were present and there were no acid radicals.

CLINICAL STUDY:

All the necessary investigations were carried out to all patients and trial drug were given. Weekly once follow up were done. Total duration of treatment ranges from 48 days. All the patients were strictly advised to follow diet restriction and peaceful life style to normalize the immune mechanism.

I got IEC Approval from Govt. Siddha Medical College, Chennai, Tamil nadu for clinical studies, IEC Approval No: GSMC-CH-ME-4/2015/004, CTRI NO: CTRI/2017/05/008576.

Age Distribution

Women with the reproductive age of 18 – 45 were affected with leucorrhoea. Among them the incidence is more in the age group 31 – 40 years which is about 30%, in the age group of 18 – 20 years were about 5%, in the age group of 21 – 25 years were about 10%, in the age group of 26- 30 years were about 25%, in the age group of 41 -45 years were about 0%.

Occupational reference

55% of patients were house wife, 15% of patients were student, 15% of patients were working women, and 15% of patients were IT- profession. Excessive stress and poor hygiene is the most cause of leucorrhoea so house wife gained higher percentage.

Socio economic status

According to the study nearly 10cases (50%) were from low income and 6 cases (30%) from lower- middle income and 3 cases (15%) from upper- middle income. The people living in poor Socio Economic Status were more affected because of life style and environmental factors.

Food habits

55% of patients have mixed diet and 45% of patients were vegetarians.

Marital status

90% of patients were married and 10% of patients were unmarried. Leucorrhoea is a sexually transmitted disease so most of the patients are married women.

Paruvakaalam

35% of patients were reported in *Pinpani kaalam* (Mid Feb – Mid Apr), 25% of patients were reported in *Kaar kaalam* (Mid Aug – Mid Oct), 25% of patients were reported in *Munpani kaalam* (Mid Dec – Mid Feb), and 15% of patients were reported in *koothir kaalam* (Mid Oct- MidDec)

Distribution of Thinai

Most of the patients about 70% were from Neithal Nilam and 30% of patients were from Marutham Nilam.

Yaakkal ilakkanam

According to the study, nearly 6 cases (30%) have *Vatha pitha yaakkai*, 2 cases (10%) have *Vatha kabha yaakkai*, 9 cases (45%) have *Pitha vatha yaakkai*, 2 cases (10%) have *Pitha kabha yaakkai*, 1 case (5%) have *kabha vatha yaakkai*. The derangement of *Pitha* which is the main cause of disease, most of the patients about *Pitha vatha yakkai.*

Duration of illness prior toTreatment

According to the study, 10 cases (50%) had a duration illness below 6 months.

Mukkutram

Vatham:

Abaanan (100%), *Viyanan* (100%), *Samaanan* (10%), and *Devathathan* (40%) were affected.

- Affected *Abaanan* results in causing Constipation.
- Affected *Viyanan* results in causing lower abdominal pain and low back ache, headache and body pain.
- Affected *Samaanan* results in loss of appetite.
- Affected *Devathathan* results in producing indigestion and tiredness.

Pitham:

Saathagam (100%), *Ranjagam* (40%) and *Praasagam* (100) were affected.

- Affected *Saathaga Pitham* results in causing general malaise, tiredness and giddiness
- Affected *Ranjaga Pitham* results in producing pallor of skin and tongue.
- Affected *Praasagam* results in Itching present in vaginal region and Tenderness.

Kabham:

Santhigam (100%) were affected.

- Affected *Santhigam* results in producing low back ache.

Udal Thathukkal:

Saaram (100%), *Senneer* (40%), *Enbu* (100%), and *Oon* (35%) were affected.

- Affected *Saaram* results in causing loss of appetite and tiredness.
- Affected *Senneer* results in causing pallor of the skin and decreased level of haemoglobin in blood.
- Affected *Enbu* results in producing Low back ache.
- Affected *Oon* results in producing Tenderness.

Envagai Thaervugal:

Among 20 patients,

Naa (40%), *Niram* (40%), *Mozhi* (60%), *Vizhi* (40%), *Malam* (80%), *Moothiram* (75%), *Sparisam* (100%) and *Naadi* (100%) were affected.

- Affcted *Naa* produced in coating of tongue.
- Affected *Niram* results in pallor of the Tongue and skin.
- Affected *Mozhi* results in low pitched voice.
- Affected *Vizhi* explains the low level of haemoglobin.
- Affected *Malam* was due to constipation.
- Affected *Moothiram* produced in Dysuria
- Affected *Sparisam* results in Itching present in vaginal region.
- Affected *Naadi* in all patients

Naadi

According to the study mostly affected *Naadi* is *Pitha vatham* (65%), *Vatha pitham* (25%)

Neikuri

Pitha Neer (80%), *Vatha Neer* (10%), and *Kabha Neer* (10%) were observed.

Clinical Manifestation

According to the study, all cases (20) (100%) had Whitish (curdy like)/ Yellowish discharge, pruritis vulva, Low backache and lower abdominal pain.

Results after treatment clinical prognosis

According to the study, the patients after treated with Siddha herbal formulation *Aghil kattai chooranam*, the symptoms such as whitish discharge, foul smelling discharge, pruritis vulva, dysuria, low backache and lower abdominal pain, infection due to *Candida albicans*, infection due to *Garenerella vaginalis*, constipation was reduced greatly and the health was well improved as 65%, 100%, 85%, 100%, 85%, 0%, 100%, 100% respectively.

Improvement

Among the total 20 patients all were improved both subjectively and objectively. Clinical symptoms before and after treatment were noted. To obtain prognosis of each clinical symptom, the following formulae was used

$$\frac{\text{No of cases after treatment}}{\text{No of cases before treatment}} \times 100$$

Infection by organism

Out of 20 patients, 14 Patients (70%) were affected by *Gardnerella vaginalis,* 6 Patients (30%) were affected by *Candida albicans.* Most common Infection is by *Gardnerella Vaginalis.*

Vaginal smear

After treatment, 6 patients (30%) were affected by *Candida albicans*, 14 patients (70%) had no growth in their wet mount test.

Overall results

Out of 20 cases, 14 cases (70%) had good results, 6 cases (30%) had Poor results.

Biostatistical report

Inference:

Since the p value *P<0.05; **P<0.01 is significant in all signs and symptoms except infection due to *candida albicans.* So there is significant reducing of signs & symptoms except infection due to *Candida albicans* among the patients for the treatment of *Vellai noi*. Hence it is concluded that the treatment was effective and **significant.**

SUMMARY

The clinical study on *Vellai noi* was carried out in Post graduate department of Maruthuvam, Government Siddha Medical College, Aringnar Anna Hospital, and Chennai – 106 during the period of 2015-2017.

A total of 20 patients were treated in the Outpatient department. The clinical and pathological assessment was carried out on the basis of Siddha and Modern aspects.

All the patients were treated with *Aghil kattai chooranam* (1 gm BD daily with Butter after food). The duration of the treatment was 48 Days.

- The comparatively larger incidence of Leucorrhoea was found to be in 31- 40 years of age.
- Out of 20 patients, House wife's occupy the first place in occupational classification.
- The prevalence of the disease was high among Middle class populations 30% followed by Lower class 50% and High class population were about 15%
- In case of diet, 55% consume mixed diet.
- Higher incidence of cases were noted in *Pinpani kalam* (35%) (Mid Feb – Mid Apr)
- Out of 20 patients, 70% comes under *Neithal thinai* category.
- In *mukkutram* aspect- In *Vatham*

  Abanan (100%), *Viyanan* (100%), *Samanan* (10%), and *Devathathan* (40) % were affected.
- In *Pitham -Sathagam* (100%), *Ranjagam* (40%) and *Praasagam* (100%) were affected.
- In *Kabham - Santhigam* (100%) were affected.
- Among *Ezhu Udal Thathukkal*, *Saaram* (100%), *Senneer* (40%), *Oon* (35%), *Enbu* (100%) were affected.
- Among *Envagai Thaervugal*, *Naa* (40%), *Niram* (40%), *Mozhi (*60%), *Vizhi* (40%), *Sparisam* (100%), *Malam* (80%), *Moothiram* (75%), *Naadi* (100%) were affected.
- *Naadi* showed *Pitha vatha naadi* (65%) and *Vatha Pitha naadi* (25%).
- In *Neikuri* examination 80% were having *pitha neer*.

- The ingredients of trial medicines were found to have the properties of reducing the symptoms of ***Vellai noi***. In *Aghil kattai chooranam* basic radicals Iron, Calcium, Reducing sugar, were present.
- The Toxicological studies of the trial medicines reveal no toxicity.
- The Pharmacological studies of the trial medicine shows Anti-bacterial activity
- The Bio statistical report of the clinical trial shows significant P value <0.01 and concluded that, the treatment is effective and significant.
- Among 20 patients, 70% of cases showed good result and 30% of cases showed poor response in *Vellai noi* (LEUCORRHOEA).

CONCLUSION

- Leucorrhoea is primarily due to the derangement of *Pitha kutram*. The ingredients of the trial medicine *Aghil kattai chooranam* have the properties of neutralizing the deranged *kutram.*
- The ingredients of the *Aghil kattai chooranam* are easily available.
- The *Aghil kattai chooranam* is economical and palatable.
- From the preclinical toxicity studies, the *Aghil kattai chooranam* revealed no toxicity and proved to be safe.
- From the preclinical pharmacological studies, it is evident that the *Aghil kattai chooranam* have Antibacterial activity.
- No Adverse effect was reported during the course of the treatment.
- The *Aghil kattai chooranam* which gives a maximum relief from the considerable symptoms of Leucorrhoea such as Whitish (Curdy like)/ Yellowish discharge, Foul smelling discharge, Pruritis vulva, Dysuria, Low backache and Lower abdominal pain, Constipation.
- The Bio statistical report of the clinical trial shows significant P value <0.01 and concluded that, the treatment is effective and significant.

Therefore I conclude that, the *Aghil kattai chooranam* can give a better solution to cure *Vellai noi*.

The Tamil Nadu Dr.M.G.R. Medical University

#69, Anna salai, Guindy, Chennai-600 032.

This certificate is awarded to

Dr./Mr./Ms. ...X...HELEN...SATHYA.....

for participating as ~~Resource Person~~ / Delegate in the First Workshop on

"Pre-clinical Studies in Research"

for Faculties & PG students of ASU Systems

Organised by the Department of Siddha,

The Tamil Nadu Dr. M.G.R. Medical University on 16.12.2014

Dr. N. KABILAN M.D. (Siddha)
Reader, Dept. of Siddha

Dr. JHANSI CHARLES M.D.
Registrar

Prof. Dr. D. SHANTHARAM, M.D., D.Diab.,
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Government Siddha Medical College
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NSK Nagar,
Arumbakkam, Chennai,
Tamil Nadu 600106.

AUTHENTICATION CERTIFICATE

Based upon the organoleptic/macroscopic/microscopic examination of fresh/market sample, it is certified that the specimen given by Dr. X. Helen Sathiya BSMS studying MD (S), Government Siddha Medical College, Arumbakkam, Chennai is identified below

Binomial name	Family	Regional names
Strychnos potatorum	Loganiaceae	Tamil: Thettran
Alpinia officinarum	Zingiberaceae	Tamil: Chitra arathai
Cynodon dactylon	Poaceae	Tamil: Arugam pul
Elettaria cardamomum	Zingiberaceae	Tamil: Ellam
Syzygium aromaticum	Myrtaceae	Tamil: Kirambu
Foeniculum vulgare	Umbelliferae	Tamil: Sombu
Glycyrrhiza glabra	Fabaceae	Tamil: Athimathuram
Cinnamomum tamala	Lauraceae	Tamil: Elavanga pattai
Psoralea corlyfolia	Fabaceae	Tamil: Karpokil arisi
Wightia tinctoria	Apocynaceae	Tamil: Vetpalai
Satalum album	Santalaceae	Tamil: Santhanam
Aquilaria agallocha	Thymelaceae	Tamil: Akil

Dr. S. Sankaranarayanan M.Sc., M.Phil., Ph.D.,

Dr.S. SANKARANARAYANAN, M.Sc.,M.Phil.,Ph.D.,
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Govt. Siddha Medical College,
Arumbakkam, Chennai-600 106.

GSMC/MB-05/2016

Date:02.06.2016

CERTIFICATE

This is to certify that the project entitled "**SAFETY EVALUATION OF *AGHIL KATTAI CHOORANM* BY ACUTE TOXICITY -OECD 423 AND SUB-ACUTE REPEATED DOSE ORAL TOXICITY STUDY- OECD 407 IN RATS**" has been approved by the IAEC of Sathyabama University, Chennai.

IAEC Approval No.: **SU/CLATR/IAEC/IV/016/2016**
Animal Sanctioned: *Rattus norvegicus* / Wistar albino rats
Male: 6; Female: 12; Total: 18 (Eighteen)

Date: 5.3.2016

DR.B.SHEELA RANI
Chair Person

DR.R.ILAVARASAN
CPCSEA Main Nominee

LABORATORY ANIMAL TECHNOLOGY AND RESEARCH (CLATR) • CENTRE FOR •
SATHYABAMA UNIVERSITY
Chennai - 600 119

Project Report on Toxicity Profiling of Akil Kattai Chooranam

Name	Dr. X. Helen Sathiya
IAEC	SU/CLATR/IAEC/IV/016/2016
Name of the Formulation	Akil Kattai Chooranam
Abbreviation	AC

ACUTE TOXICITY STUDY

Acute toxicity study of the study drug *Akil Kattai Chooranam* was carried out as per OECD guideline (Organization for Economic Co-operation and Development) Guideline-423.

Animal

Healthy adult Wistar albino rat weighing between 170-200 g were used for the study. The animals were housed in poly propylene cages and were kept in well ventilated with 100% fresh air by air handling unit (AHU). A 12 light / dark cycle were maintained .Room temperature was maintained between 22 $\pm$ 2^0 C and relative humidity 50–65%. They were provided with food (Sai feeds, Bangalore, India) and water *ad libitum*. All the animals were acclimatized to the laboratory for 7 days prior to the start of the study.

The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India.

Acute toxicity Study

Acute toxicity study will be carried out in accordance with OECD guideline 423 [81]. The animals were fasted overnight with free access to water. The study was conducted with single oral dose administration of *Akil Kattai Chooranam*.

IAEC SU/CLATR/IAEC/IV/016/2016

Animal Grouping

One group consist of 6 female rats were used for this study. The dose utilized for evaluation of acute toxicity study is about 2000 mg/kg higher than that of the therapeutic dose.

Animal Grouping

GROUP I: Animals received Test drug 2000 mg/kg (p.o)

The animals were fasted overnight (12- 16 hrs) with free access to water. The study was conducted with single oral administration of study drug *Akil Kattai Chooranam* 2000mg/kg (p.o). The animals were observed continuously for first 72 h and then 14 days for emerging signs of behavioral changes, body weight changes and for mortality.

Occurrence of toxicity in animals were observed continuously for the first 4 to 24 h and observed periodically for the next 14 days. Observation includes the change in skin, fur, eyes and mucus membrane. Appearance of C.N.S,C.V.S and A.N.S related toxicity such as tremors, convulsions, sedation, steric behavior, respiratory distress, cardiovascular collapse, response to sensory stimuli, salivation, diarrhea, lethargy, sleep, coma and mortality were observed with special attention.

Body weight was recorded periodically. At the end of the experiment all animals were subjected for gross necropsy and observed for pathological changes.

SUB-ACUTE TOXICITY STUDY

Sub-acute toxicity study was carried out as per OECD guidelines Guideline-407 [82].

Animals

Healthy adult Wistar albino rat weighing between 170-200 g were used for the study. The animals were housed in poly propylene cages and were kept in well ventilated with 100% fresh air by air handling unit (AHU). A 12 light / dark cycle were maintained .Room temperature was maintained between 22 $\pm$ 2^{o} C and relative humidity 50–65%. They were provided with food (Sai feeds, Bangalore, India) and water *ad libitum*. All the animals were acclimatized to the laboratory for 7 days prior to the start of the study.

The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India.

IAEC SU/CLATR/IAEC/IV/016/2016

Animal Grouping

Animals were divided into three groups of 06 animals each consist of 3 male and 3 female rats.

GROUP I : Animals received saline 5 ml/kg b.w (p.o)

GROUP II : Animals received low dose of test drug 200 mg/kg (p.o)

GROUP III : Animals received high dose of test drug 400 mg/kg (p.o)

The animals were randomly divided into control group and drug treated groups for two different doses viz. low dose (200 mg/kg b.w) and high dose (400 mg/kg b.w).

The animals were administrated with the study drug once daily for 28 days. The animals in group I (control group) received normal saline 5 ml/kg b.w. The animals in group II received low dose of *Akil Kattai Chooranam* 200 mg/kg b.w (p.o) and group III received high dose of *Akil Kattai Chooranam* 400 mg/kg b.w (p.o).

The rats were weighed periodically and observed for signs of toxicity pertains to C.N.S, C.V.S, A.N.S including behavioral changes, food - water intake and morphological changes. At the end of 28^{th} day, the animals were fasted for overnight with free access to water. On 29^{th} day the animals were sacrificed with excess anesthesia. Blood samples were collected from aorta and stored in EDTA (ethylenediamine –tetra actate) for Hematological analysis and for serum generation for biochemical analysis.

The vital organs including heart, brain, lungs, spleen, kidneys, liver, stomach, testes, and ovary were harvested and carefully examined for gross lesions. The organs were preserved in 10% formalin for histopathological assessment and interpretation.

Hematological analysis

Blood samples were analyzed using established procedures and automated Bayer Hematology analyzer. Parameters evaluated include Packed Cell Volume (PCV), Red Blood Cells (RBC) count, White blood cell count (WBC), Platelet Count, Hemoglobin (Hb), Mean cell Haemoglobin Concentration (MCHC), Mean Red Cell Volume (MCV), Mean Cell Hemoglobin (MCH), Mean platelet volume (MPV), Neutrophils, Eosinophil's, Basophils, Lymphocytes and Monocytes.

Biochemical analysis [83]

Serum samples were analyzed for High Density Lipoprotein (HDL), Low density Lipoprotein (LDL) , Very low density Lipoprotein (VLDL) , Triglycerides

(TGL), Total Cholesterol , Blood urea nitrogen (BUN), Creatinine, Albumin, Total Protein, Glucose, Uric acid, Aspartate Transaminase (AST), Alanine amino Transaminase (ALT) and Alkaline Phosphatase (ALP) using Mind ray auto analyzer model BS 120.

Histopathological evaluation [84]

Organs included of heart, brain, lungs, spleen, kidneys, liver, stomach, testes and ovary. Histological slides of organs were made and observed under the microscope. The pathological observations of cross section of these organs were performed on gross and microscopic bases. Histological examinations were performed on the preserved tissues with particular emphasis on those which showed gross pathological changes.

Statistical analysis

The statistical analysis was carried by one way ANOVA (GRAPH PAD PRISM 5 computer program). Results were expressed as mean ± standard error .A statistical comparison was carried out using the Dunnet's test for the control and treatment group.

Faecal Pellet Analysis

Methodology

Rats of control and treatment group were allowed to explore to open field on clean and sterile Stainless steel tray. The collected pellets were analysed for consistency, colour, Shape, Presence of blood cells etc.

ACUTE TOXICITY	
Analysis	**Group I**
Consistency	Soft
Shape	Oblong
Colour	Dark Brown
Mucous Shedding	Absence

Blood Cells	Absent
Signs of Infection	None Observed

SUB-ACUTE TOXICITY STUDY			
Analysis	**Group I**	**Group II**	**Group III**
Consistency	Soft	Soft	Soft
Shape	Oblong	Pointed Head	Pointed Head
Colour	Brownish green	Brownish green	Brownish green
Mucous Shedding	Absence	Absence	Absence
Blood Cells	Absent	Absent	Absent
Signs of Infection	None Observed	None Observed	None Observed

Muscle Grip Strength Analysis

The grip strength test is a simple non-invasive method designed to evaluate rat muscle force in vivo. Rats of control and drug treated group was allowed to hold the pull bar with both the hind limbs firmly then the animal was gently pulled back with the tail until the animal lost the grip toward the bar. The procedure was repeated to get the average value. Muscle grip ness of the drug treated group was compared to that of the control rat to ensure the change in coordination.

Metabolic Cage for Urine Collection

Rat of control and treatment group was placed individually in metabolic cage with free access to feed and water. Urine dropping from the animal was collected using specialized wire mesh system fixed at the base of the cage having provision to trap the fecal pellet mixed with urine sample. The collected urine sample was subjected to analysis with respect to colour, pH, glucose, ketone bodies, pus and blood cells.

RESULTS

Assessment of clinical signs in rats treated with *Akil Kattai Chooranam* on Acute toxicity study

Parameter	Group I
Clinical Signs Parameters for the duration of 14 days	Test Drug 2000mg/ Kg
Number of animals observed	6 Female
Lacrimation	Absence
Salivation	Absence
Animal appearance	Normal
Tonic Movement	Absence
Clonic Movement	Absence
Laxative action	Absence
Touch Response	Normal
Response to Sound	Normal Response
Response to Light	Normal Response
Mobility	Normal Response
Respiratory Distress	Nil
Skin Colour	Normal
Stereotype behaviour	Absence
Piloerection	Absence
Limb Paralysis	Absence
Posture	Normal
Open field behaviour	Normal
Gait Balancing	Normal
Freezing Behaviour	Absent
Sings of Stress and Anxiety	None Observed
Muscular coordination	Normal
Muscle grip	Normal
Sedation	Absence
Social Behavior	Normal
Urine Analysis	No Abnormality
Urine Colour	Yellowish
Urine pH	7

Urine -Glucose	Absence
Urine -Ketones	Absence
Urine- Bilirubin	Absence
Urine-Blood Cells	Negative
Urine - Pus cells	Negative
Mortality	Nil

Quantitative data on the body weight of rats treated with *Akil Kattai Chooranam* in Acute toxicity study

Group I	**Before Treatment Weight in Gms**	**After Treatment Weight in Gms**
Mean	181.8	184.5
Std. Deviation	6.94	7.868
Std. Error	2.833	3.212

Values are mean ± S.D (n = 6 per group). Control and treatment group were compared statistically using one way ANOVA followed by Dunnett's test.

Assessment of clinical signs in rats treated with *Akil Kattai Chooranam* on Sub-Acute toxicity study

Parameter	**Group I**	**Group II**	**Group III**
Clinical Signs Parameters for the duration of 28 days	Control	Test Drug 200mg/ Kg	Test Drug 400mg/ Kg
Number of animals observed	3 Male and 3 Female	3 Male and 3 Female	3 Male and 3 Female
Lacrimation	Absence	Absence	Absence
Salivation	Absence	Absence	Absence
Animal appearance	Normal	Normal	Normal
Tonic Movement	Absence	Absence	Absence
Clonic Movement	Absence	Absence	Absence
Absence	Absence	Absence	Absence
Touch Response	Normal	Normal	Normal
Response to Sound	Normal Response	Normal Response	Normal Response
Response to Light	Normal Response	Normal Response	Normal Response
Mobility	Normal	Normal	Normal
Respiratory Distress	Nil	Nil	Nil
Skin Colour	Normal	Normal	Normal

Stereotype behaviour	Absence	Absence	Absence
Piloerection	Absence	Absence	Absence
Limb Paralysis	Absence	Absence	Absence
Posture	Normal	Normal	Normal
Open field behaviour	Normal	Normal	Normal
Gait Balancing	Normal	Normal	Normal
Freezing Behaviour	Absent	Absent	Absent
Sings of Stress and Anxiety	None Observed	None Observed	None Observed
Muscular coordination	Normal	Normal	Normal
Muscle grip	Normal	Normal	Normal
Sedation	Absence	Absence	Absence
Social Behaviour	Normal	Normal	Normal
Urine Analysis	No Abnormality	No Abnormality	No Abnormality
Urine Colour	Yellowish	Pale Yellow	Pale Yellow
Urine Ph	6	6	6
Urine -Glucose	Absence	Absence	Absence
Urine -Ketones	Absence	Absence	Absence
Urine- Bilirubin	Absence	Absence	Absence
Urine-Blood Cells	Negative	Negative	Negative
Urine - Pus cells	Negative	Negative	Negative
Mortality	Nil	Nil	Nil

Effect of *Akil Kattai Chooranam* on Body weight of Rats in Sub-acute toxicity study

Group I	**Before Treatment Weight in Gms**	**After Treatment Weight in Gms**
Mean	187.3	198.7
Std. Deviation	5.645	6.408
Std. Error	2.305	2.616
Group II	**Before Treatment Weight in Gms**	**After Treatment Weight in Gms**
Mean		
Std. Deviation		
Std. Error		
Group III	**Before Treatment**	**After Treatment Weight in Gms**
Mean		
Std. Deviation		
Std. Error		

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Quantitative data on the food and water intake of rats treated with *Akil Kattai Chooranam* for 28 days in Sub-acute toxicity study

Group I	**Food intake**	**Water intake**
Mean	16.08	20.42
Std. Deviation	2.47	5.984
Std. Error	1.235	2.992
Group II	**Food intake**	**Water intake**
Mean	17.5	35.17
Std. Deviation	1.139	0.6383
Std. Error	0.5693	0.3191
Group III	**Food intake**	**Water intake**
Mean	16.92	40.17
Std. Deviation	3.957	2.046
Std. Error	1.978	1.023

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Effect of *Akil Kattai Chooranam* on Haematology profile of rats in sub-acute toxicity study.

Group I	**WBC count ($\times 10^3$ µl)**	**RBC ($\times 10^6$ µl)**	**PLT ($\times 10^3$ µl)**	**MCV (fl)**	**MCH (pg)**	**MCHC (g/dl)**	**HGB (g/dl)**
Mean	7.983	5.683	506.2	56.35	17.98	31.78	12.04
Std. Deviation	2.408	0.9347	311.2	4.615	2.771	2.477	2.252
Std. Error	0.983	0.3816	127	1.884	1.131	1.011	0.9193
Group II	**WBC count ($\times 10^3$ µl)**	**RBC ($\times 10^6$ µl)**	**PLT ($\times 10^3$ µl)**	**MCV (fl)**	**MCH (pg)**	**MCHC (g/dl)**	**HGB (g/dl)**
Mean	11.38	6.383	640.5	60.23	20.62	34.15	12.6
Std. Deviation	2.32	1.336	212	8.779	2.328	2.895	2.254
Std. Error	0.9471	0.5455	86.54	3.584	0.9506	1.182	0.9201

Group III	**WBC count ($\times 10^3$ µl)**	**RBC ($\times 10^6$ µl)**	**PLT ($\times 10^3$ µl)**	**MCV (fl)**	**MCH (pg)**	**MCHC (g/dl)**	**HGB (g/dl)**
Mean	11.27	6.817	696.8	60.25	19.82	30.78	12.28
Std. Deviation	2.991	1.222	328.5	8.298	2.583	1.261	2.309
Std. Error	1.221	0.4989	134.1	3.388	1.054	0.5147	0.9428

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Effect of *Akil Kattai Chooranam* on Haematology profile of rats in sub-acute toxicity study.

Group I	**Lymph (%)**	**Mon (%)**	**Neutrophils (X 10^3/mm^3)**	**Eosinophils (%)**	**Basophils (%)**	**MPV (fl)**
Mean	75.23	2.4	2.1	1.217	0.3333	5.2
Std. Deviation	10.23	1.255	0.4	0.3061	0.5164	1.664
Std. Error	4.175	0.5125	0.1633	0.1249	0.2108	0.6792
Group II	**Lymph (%)**	**Mon (%)**	**Neutrophils (X 10^3/mm^3)**	**Eosinophils (%)**	**Basophils (%)**	**MPV (fl)**
Mean	72.92	3.267	2.2	1.4	0.3333	5.383
Std. Deviation	9.102	0.9223	0.7211	0.1549	0.5164	1.207
Std. Error	3.716	0.3765	0.2944	0.06325	0.2108	0.4929
Group III	**Lymph (%)**	**Mon (%)**	**Neutrophils (X 10^3/mm^3)**	**Eosinophils (%)**	**Basophils (%)**	**MPV (fl)**
Mean	84.77	3.65	2.55	1.55	0.1667	5.533
Std. Deviation	6.941	1.669	1.244	0.3391	0.4082	0.8116
Std. Error	2.834	0.6815	0.5078	0.1384	0.1667	0.3313

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Effect of *Akil Kattai Chooranam* on Serum Bio-chemistry profile of rats in sub-acute toxicity study

Group I	**Blood sugar ® (mg/dl)**	**BUN (mg/dl)**	**Serum creatinine (mg/dl)**	**Serum total cholesterol (mg/dl)**	**Serum triglycerides level (mg/dl)**	**Serum HDL cholesterol (mg/dl)**	**Serum LDL cholesterol (mg/dl)**	**Serum VLDL cholesterol (mg/dl)**
Mean	67.17	14.33	0.4333	110.3	79.5	49.17	35.5	12.98
Std. Dev	7.167	4.457	0.08165	22.6	16.26	7.96	17.42	3.277
Std. Error	2.926	1.82	0.03333	9.226	6.637	3.25	7.112	1.338
Group II	**Blood sugar ® (mg/dl)**	**BUN (mg/dl)**	**Serum creatinine (mg/dl)**	**Serum total cholesterol (mg/dl)**	**Serum triglycerides level (mg/dl)**	**Serum HDL cholesterol (mg/dl)**	**Serum LDL cholesterol (mg/dl)**	**Serum VLDL cholesterol (mg/dl)**
Mean	80.17	15.67	0.6	128.8	88.67	60	35.83	17.58
Std. Dev	13.27	4.967	0.228	9.131	14.45	23.35	14.47	2.891
Std. Error	5.419	2.028	0.09309	3.728	5.897	9.532	5.907	1.18
Group III	**Blood sugar ® (mg/dl)**	**BUN (mg/dl)**	**Serum creatinine (mg/dl)**	**Serum total cholesterol (mg/dl)**	**Serum triglycerides level (mg/dl)**	**Serum HDL cholesterol (mg/dl)**	**Serum LDL cholesterol (mg/dl)**	**Serum VLDL cholesterol (mg/dl)**
Mean	80.5	9.167	0.65	105.8	76.33	65	33.5	14.45
Std. Dev	18.22	2.137	0.1871	15.79	7.554	15.58	13.58	2.52
Std. Error	7.438	0.8724	0.07638	6.447	3.084	6.361	5.542	1.029

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Effect of *Akil Kattai Chooranam* on Serum Bio-chemistry profile of rats in sub-acute toxicity study

Group I	**Serum total protein (g/dl)**	**Serum albumin (g/dl)**	**(AST) (IU/ml)**	**(ALT) (IU/L)**	**(ALP) (IU/L)**
Mean	3.633	2.917	131.2	31.83	155.3
Std. Deviation	0.9668	0.5345	8.256	9.02	74.81
Std. Error	0.3947	0.2182	3.371	3.683	30.54

Group II	**Serum total protein (g/dl)**	**Serum albumin (g/dl)**	**(AST) (IU/ml)**	**(ALT) (IU/L)**	**(ALP) (IU/L)**
Mean	4.167	3.45	130.7	34.33	168.2
Std. Deviation	0.814	1.007	10.73	9.459	33.58
Std. Error	0.3323	0.4113	4.379	3.861	13.71
Group III	**Serum total protein (g/dl)**	**Serum albumin (g/dl)**	**(AST) (IU/ml)**	**(ALT) (IU/L)**	**(ALP) (IU/L)**
Mean	4.45	2.467	104.8	24.17	145.2
Std. Deviation	0.6348	0.5955	21.25	6.306	61.82
Std. Error	0.2592	0.2431	8.677	2.574	25.24

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Organ Gross Observation of rats treated with *Akil Kattai Chooranam* for 28 days in Sub-acute toxicity study.

Treatment Female **Treatment Male**

Quantitative data on absolute organ weight of rats treated with *Akil Kattai Chooranam* for 28 days in Sub-acute toxicity study.

Group I	**HEART (gms)**	**LIVER (gms)**	**KIDNEYS (gms)**	**SPLEEN (gms)**	**BRAIN (gms)**	**LUNG (gms)**	**STOMACH (gms)**	**TESTES (gms)**	**UTERUS & OVARY (gms)**
Mean	0.54	4.672	1.283	0.55	1.383	1.317	1.233	2.7	1.333
Std. Deviation	0.1534	0.7039	0.1236	0.2588	0.2229	0.1941	0.2251	0.6083	0.1528
Std. Error	0.06261	0.2874	0.05044	0.1057	0.09098	0.07923	0.09189	0.3512	0.08819
Group II	**HEART (gms)**	**LIVER (gms)**	**KIDNEYS (gms)**	**SPLEEN (gms)**	**BRAIN (gms)**	**LUNG (gms)**	**STOMACH (gms)**	**TESTES (gms)**	**UTERUS & OVARY (gms)**
Mean	0.7517	5.027	1.327	0.6167	1.683	1.517	1.183	2.8	1.333

Std. Deviation	0.1768	0.5882	0.1921	0.1835	0.2137	0.1941	0.3764	0.781	0.2517
Std. Error	0.07218	0.2401	0.07843	0.07491	0.08724	0.07923	0.1537	0.4509	0.1453
Group III	**HEART (gms)**	**LIVER (gms)**	**KIDNEYS (gms)**	**SPLEEN (gms)**	**BRAIN (gms)**	**LUNG (gms)**	**STOMACH (gms)**	**TESTES (gms)**	**UTERUS & OVARY (gms)**
Mean	0.7433	6.422	1.497	0.4833	1.617	1.7	1.433	3.2	1
Std. Deviation	0.2084	1.433	0.2337	0.2137	0.1941	0.2191	0.3983	1.1	0.1732
Std. Error	0.08508	0.585	0.09542	0.08724	0.07923	0.08944	0.1626	0.6351	0.1

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females) for Heart, Liver, Kidney, Brain, Spleen, Lung, Stomach. Values are mean ± S.D (n = 3 per group per sex) for testes , ovary and uterus for Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

HISTOPATHOLOGY REPORT

BRAIN

Regular marginal alignment on the neurons with promising histology .Neurons is very intact and there were no signs of oedema or degeneration were observed in sample belongs to group I, II and III.

HEART

Nucleus appears prominent with regular arrangement of fibres. No evidence of pyknotic nucleus were observed in samples belongs to group I, II and III.

LUNG

No signs of airway secretion and bronchial secretion. Bronchial blood vessels and connective tissue appears normal with no signs of pulmonary oedema

STOMACH

Intracytoplasmic zone of mucosa appears normal .Light microscopic observation stomach reveals normal histology of gastric wall composed of normal mucosa, muscularismucosa, submucosa, muscularispropiria and adventitia. No signs of ulceration were observed in sample belongs to group I, II and III.

LIVER

Centrilobular zone appears normal with stable network of hepatocytes. Rare appearance of Kupffer cells with no evidence of phagocytosis in intracytoplasmic region were observed in sample belongs to group I, II and III.

SPLEEN

Appearance of LF – lymphoid follicle; PALS – periarterial lymphoid sheath was normal with no significant signs of enlargement were observed in sample belongs to group I, II and III.

KIDNEY

Appearance of proximal and distal convolutes tubules was normal with no evidence of atrophy. Lumen of distal convolutes tubule and collecting duct was normal in sample belongs to group I, II and III.

TESTES

Presence of mature somatic cells project the perfect histomorphology of testicular cells in this group. Primary spermatocytes with large centered nucleus and dense chromatin were observed in sample belongs to group I, II and III.

UTERUS

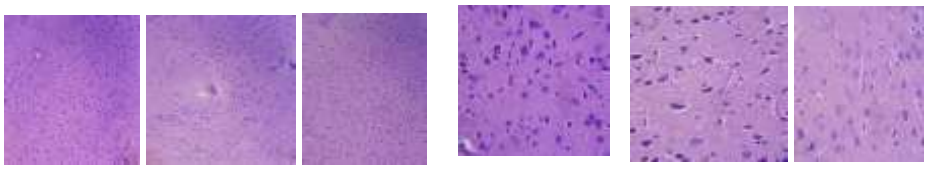
Appearance of endometrium, myometrium and uterine glands was normal. Arrangement of stratum basale, functionale and surface epithelium seems normal in samples belongs to group I, II and III.

OVARY

Histopathological analysis of ovary showing normal corpus luteum (CL) and Primordial follicles with few mature ovarian follicles with no signs of abnormality. Appearance of antral follicle, primary oocyte and secondary follicles are normal in sample belong to group I, II and III.

Histopathology of Brain (Male Rat) in Sub-acute toxicity Study

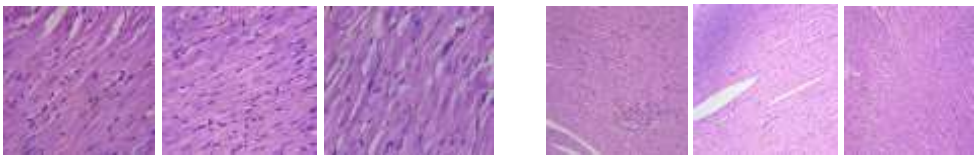
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III GROUP I GROUP II GROUP III

Histopathology of Heart (Male Rat) in Sub-acute toxicity Study

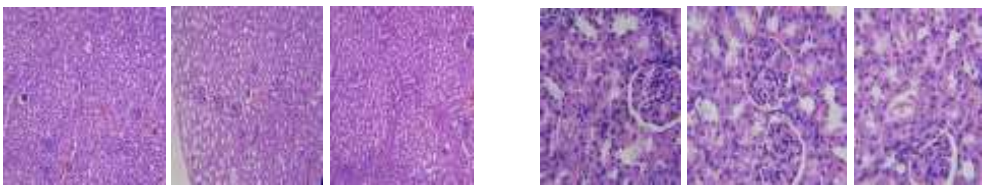
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III GROUP I GROUP II GROUP III

Histopathology of Kidney (Male Rat) in Sub-acute toxicity Study

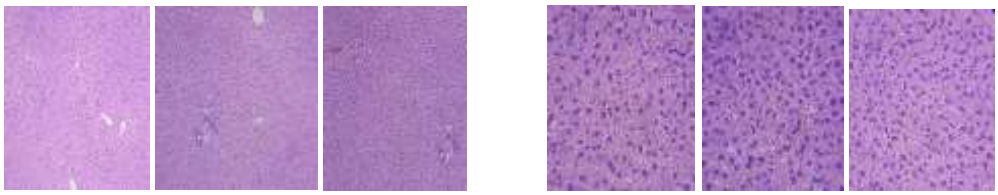
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III GROUP I GROUP II GROUP III

Histopathology of Liver (Male Rat) in Sub-acute toxicity Study

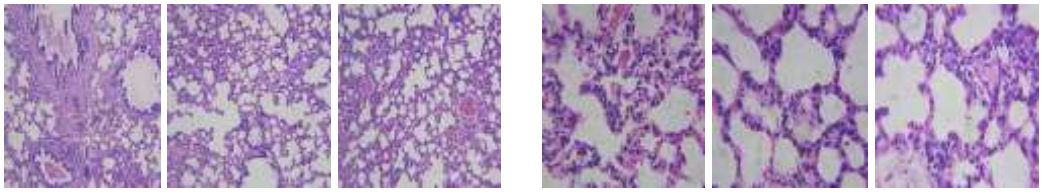
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III GROUP I GROUP II GROUP III

Histopathology of Lung (Male Rat) in Sub-acute toxicity Study

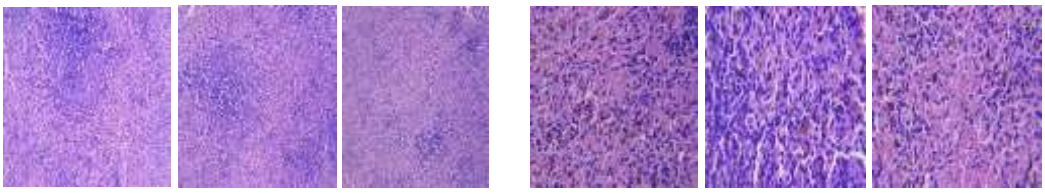
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III **GROUP I GROUP II GROUP III**

Histopathology of Spleen (Male Rat) in Sub-acute toxicity Study

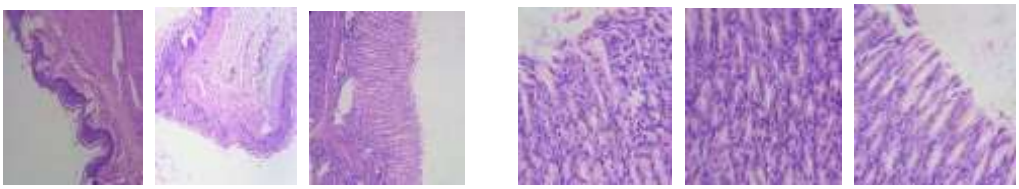
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III **GROUP I GROUP II GROUP III**

Histopathology of Stomach (Male Rat) in Sub-acute toxicity Study

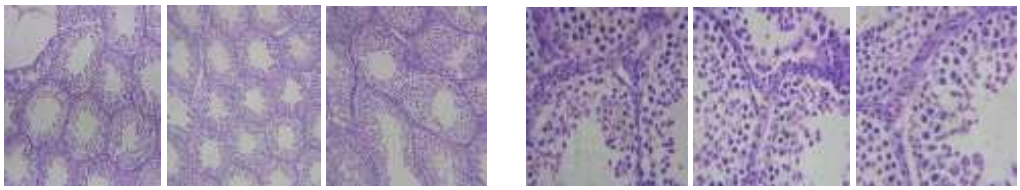
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III **GROUP I GROUP II GROUP III**

Histopathology of Testes (Male Rat) in Sub-acute toxicity Study

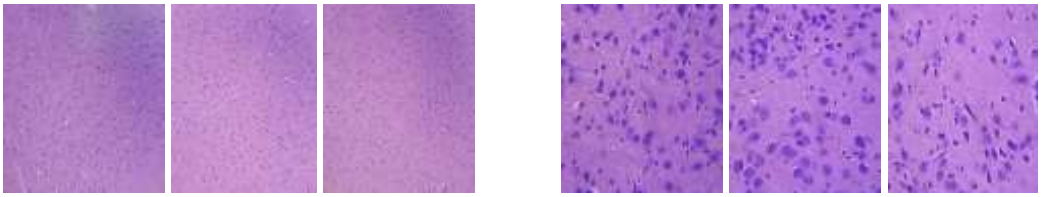
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III **GROUP I GROUP II GROUP III**

Histopathology of Brain (Female Rat) in Sub-acute toxicity Study

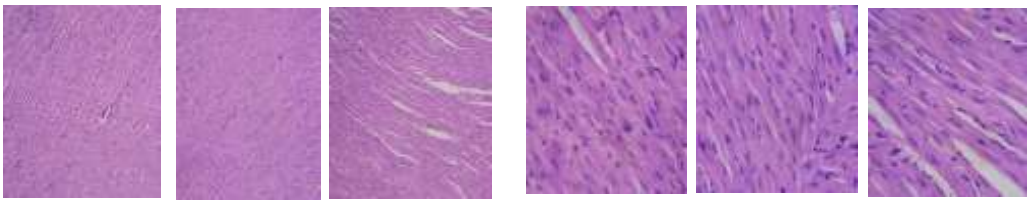
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III **GROUP I GROUP II GROUP III**

Histopathology of Heart (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III **GROUP I GROUPII GROUPIII**

Histopathology of Kidney (Female Rat) in Sub-acute toxicity Study

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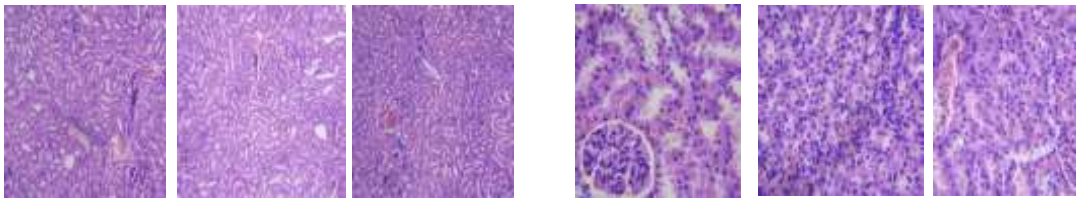

GROUP I GROUPII GROUP III **GROUPI GROUPII GROUPIII**

Histopathology of Liver (Female Rat) in Sub-acute toxicity Study

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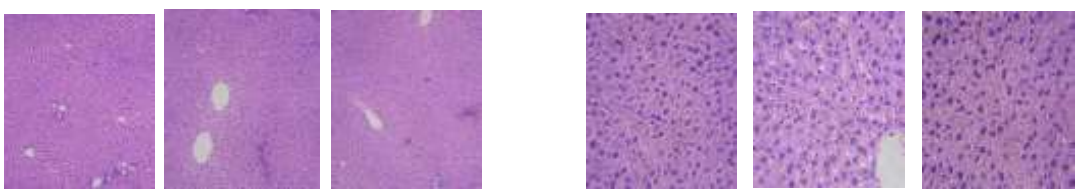
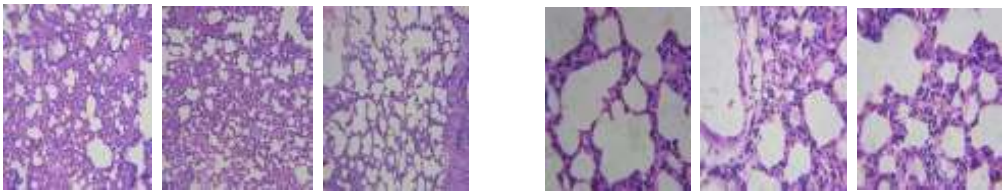


GROUP I GROUP II GROUP III **GROUP I GROUPII GROUPIII**

Histopathology of Lung (Female Rat) in Sub-acute toxicity Study

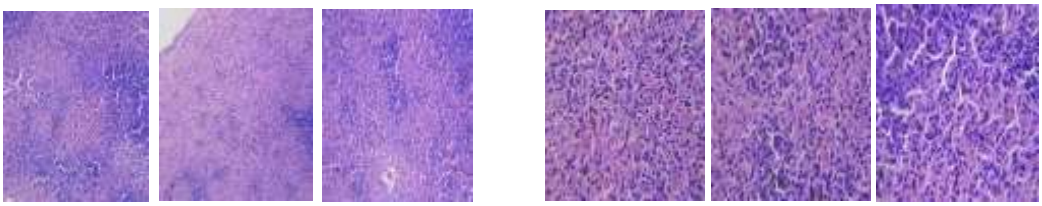
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III **GROUP I GROUP II GROUP III**

Histopathology of Spleen (Female Rat) in Sub-acute toxicity Study

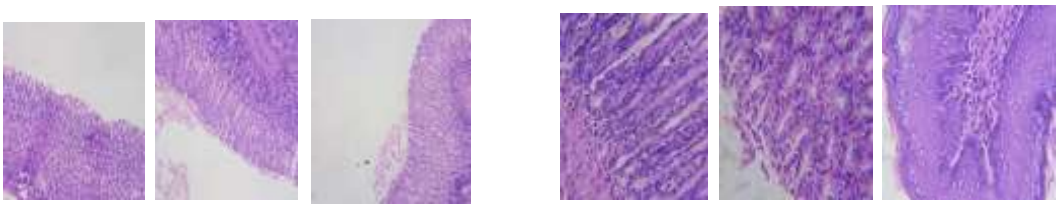
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III **GROUP I GROUP II GROUP III**

Histopathology of Stomach (Female Rat) in Sub-acute toxicity Study

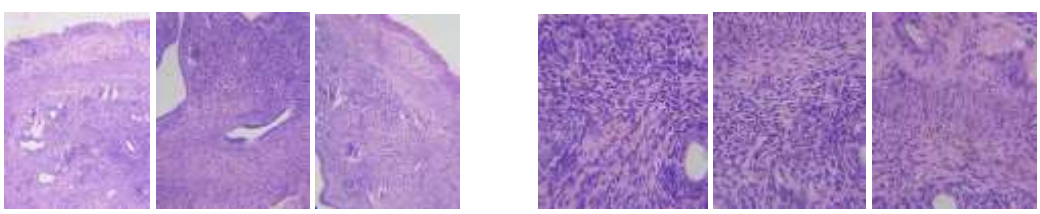
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III **GROUP I GROUP II GROUP III**

Histopathology of Uterus (Female Rat) in Sub-acute toxicity Study

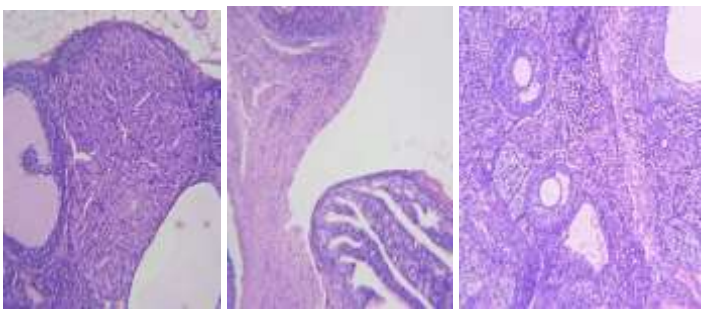
Low Power Magnification 10X **High Power Magnification 40X**



GROUP I GROUP II GROUP III **GROUP I GROUP II GROUP III**

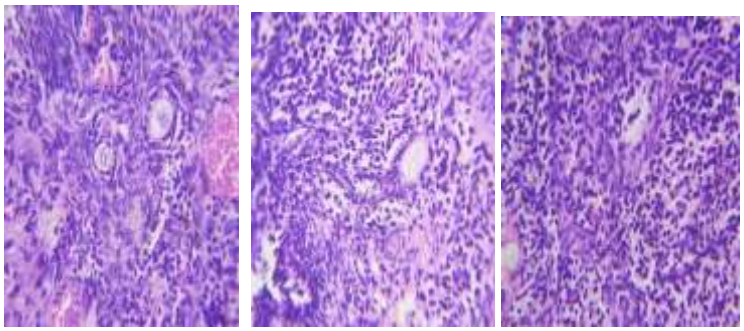
Histopathology of Ovary (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



GROUP I **GROUP II** **GROUP III**

High Power Magnification 40X



GROUP I **GROUP II** **GROUP III**

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Anti -Microbial Profiling of *Aghil kattai Chooranam* on Leucorrhoea Specific Pathogens

Issued to : Dr. X. Helen Sathiya
Formulation : Aghil kattai Chooranam
Sample ID : AKC
Mode of Analysis : Third Party Analysis

Date: 29/3/2017

Organisms used for Anti-Bacterial Activity

s.no	organisms
1.	*Gardenarella vaginalis*

Organisms used for Anti-Fungal Activity

s.no	organisms
1.	*Candida albicans*

Zone of Inhibition data of Anti-Microbial Activity in mm

Sample code	*Gardenerella vaginalis*			*Candida albicans*		
Concentration	500 µg	1000 µg	2000 µg	500 µg	1000 µg	2000 µg
MC	7	9	12	-	-	-
Metronidazole (5µg)	25			-		
Fluconazole (25µg)	NA			24		

- = Not active NA = Not Applicable

Anti -Microbial Profiling of *Aghil kattai Chooranam* on Leucorrhoea Specific Pathogens

Sample ID: **AKC**

Institute: Govt, Siddha Medical College, Chennai.

Test Organism

Organisms used for Anti-Bacterial Activity

s.no	Organisms
1.	***Gardenerella vaginalis***

Organisms used for Anti-Fungal Activity

s.no	Organisms
2.	***Candida albicans***

Anti- Bacterial Activity

Disc-diffusion method:

The antibacterial activities of the sample AKC were carried out by disc diffusion method. The concentrations of the test compounds were used at the concentration of 500, 100, 2000 µg. The target microorganisms were cultured in HBT Medium. After 24 h the cultured streaks were swabbed for study purpose .The Petri dishes containing HBT medium were cultured with *Gardenerella vaginalis*. Disc made of Whatman No.1, diameter 6 mm was pre-sterilized and was maintained in aseptic chamber. Each concentration was injected to the sterile disc papers. Then the prepared discs were placed on the culture medium. Standard drug Metronidazole (5µg) was used as a positive reference standard to determine the sensitivity of each microbial species tested. Then the inoculated plates were incubated at 35^{o} C for 48 hrs. The diameter of the clear zone around the disc was measured and expressed in millimetres as its anti-microbial property. The results were depicted in **Table.**

Disc-diffusion method:

The anti-fungal activities of the sample AKC were carried out by disc diffusion method. The concentrations of the test compounds were used at the concentration of 500, 1000, 2000 µg. The target microorganisms were cultured in Mueller–Hinton broth (MHB). After 24 h the suspensions were adjusted to standard sub culture dilution. The Petri dishes containing Muller Hinton Agar (MHA) medium were cultured with diluted bacterial strain. Disc made of Whatman No.1, diameter 6 mm was pre-sterilized and was maintained in aseptic chamber. Each concentration was injected to the sterile disc papers. Then the prepared discs were placed on the culture medium. Standard drug Fluconazole (25µg) was used as a positive reference standard to determine the sensitivity of the species tested. Then the inoculated plates were incubated at 37^{o} C for 72 hr (Fungal). The diameter of the clear zone around the disc was measured and expressed in millimeters as its anti-fungal property. The results were depicted in **Table.**

Zone of Inhibition data of Anti-Microbial Activity

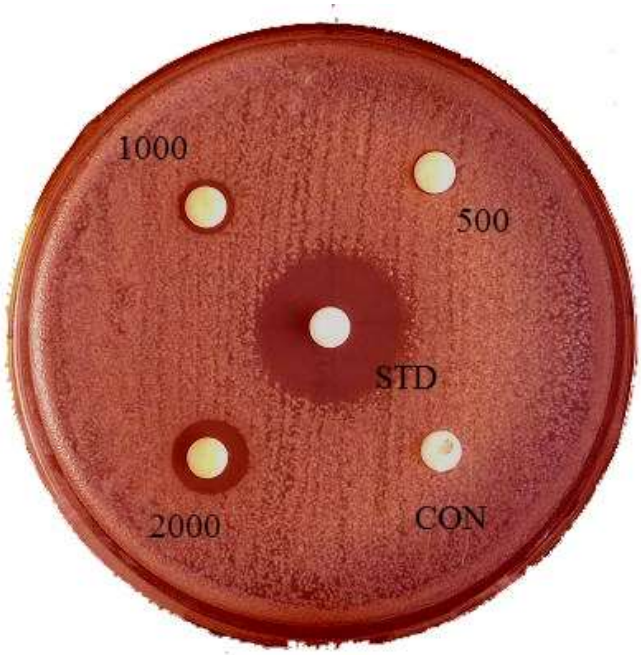
Sample code	***Gardnerella vaginalis***			***Candida albicans***		
Concentration	**500 µg**	**1000 µg**	**2000 µg**	**500 µg**	**1000 µg**	**2000 µg**
MC	**7**	**9**	**12**	-	-	-
Metronidazole (5µg)	**25**			**-**		
Fluconazole (25µg)	**NA**			**24**		

- = Not active

NA = Not Applicable

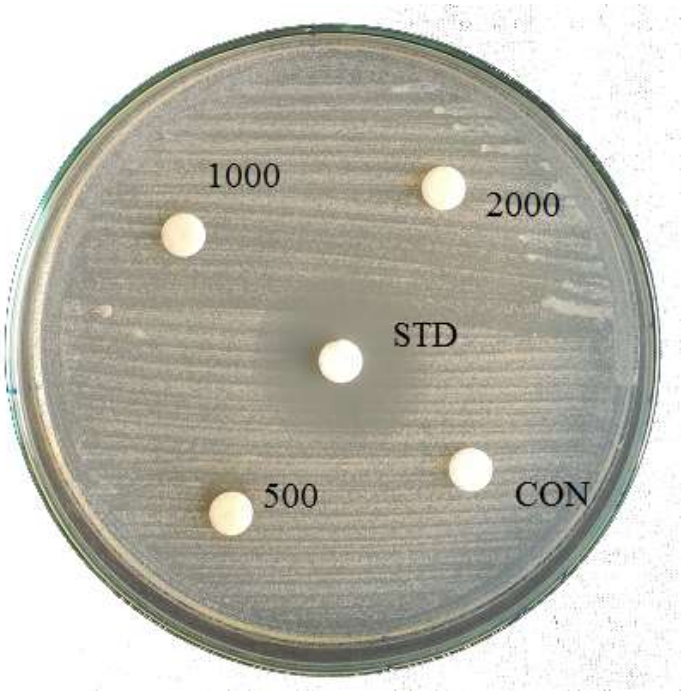
ANTI- BACTERIAL EVALUATION

Anti- Microbial Effect of AKC against *Gardenerella vaginalis*



ANTI-FUNGAL EVALUATION

Anti- Microbial Effect of AKC against ***Candida albicans***



சித்த மருத்துவ மைய ஆராய்ச்சி நிலையம், சென்னை - **600 106**
सिद्ध केंद्रीय अनुसन्धान संस्थान,
अण्णा सरकारी अस्पताल परिसर, अरुम्बाक्कम, चेन्नई – **600 106**
SIDDHA CENTRAL RESEARCH INSTITUTE
(Central Council for Research in Siddha, Ministry of AYUSH, Govt. of India)
Anna Govt. Hospital Campus, Arumbakkam, Chennai – 600106
Phone: 044-2621 4925, Fax: 044-2621 4809

20.1.2017

CERTIFICATE

Name of the student: Dr. X. Helen Sathiya, II year PG student, Pothu Maruthuvam, Government Siddha Medical College, Arumbakkam, Chennai-600 106.

Name of the sample: Aghil Kattai Chooranam

Name of the Experiment	I	II	Mean
Loss on drying(at 105°C)	7.675 %	7.405 %	7.54 %
Total ash	4.9 %	5.1 %	5.0 %
Water soluble ash	2.025 %	2.03 %	2.025 %
Acid insoluble ash	0.625 %	0.73 %	0.678 %
Water soluble extractive	20.2 %	21.7 %	20.95 %
Alcohol soluble extractive	16.97 %	19.16 %	18.06 %
pH value (10%)	6.49	6.47	6.48
TLC/HPTLC	Report Enclosed		

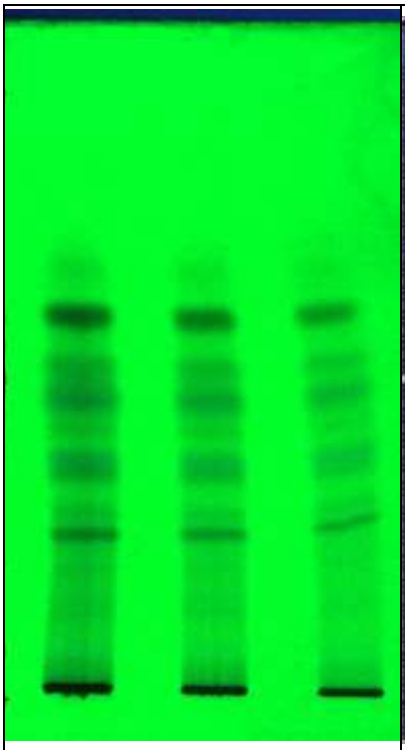
(R. Shakila)
Research Officer (Chemistry) & Head,
Department of Chemistry

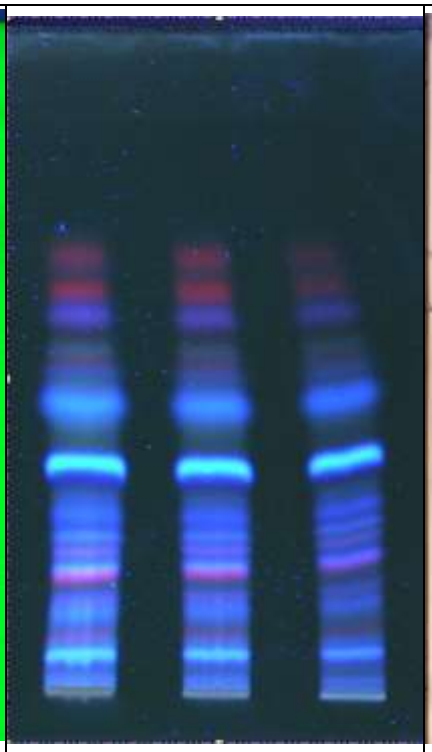
(Dr. P. Elankani)
Research Officer (Scientist II) (Siddha)
for Assistant Director (Siddha) I/c

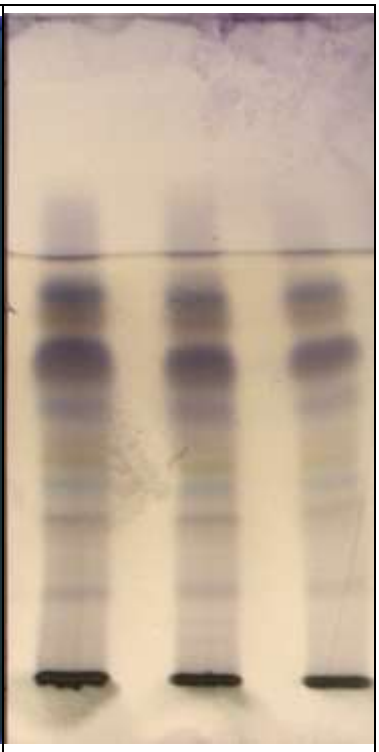
Sample Name/ID –AKC

Stationary Phase - Silica Gel 60 F_{254}

Mobile Phase – Toluene: Ethyl Acetate: Acetic Acid (4: 2: 0.5 drops v/v/v)

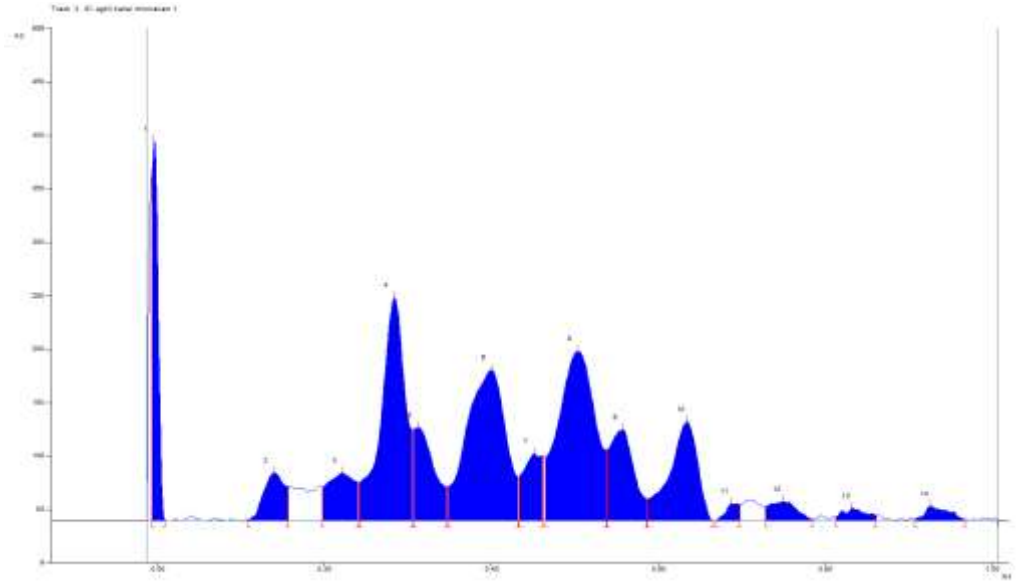






254 nm		366 nm		575 nm (Derivatized)	
Colour	**R_f value(s)**	**Colour**	**R_f value(s)**	**Colour**	**R_f value(s)**
Dark	0.26	Light Blue	0.05	Pink	0.06
Dark	0.38	Sky Blue	0.07	Violet	0.09
Dark	0.44	Light Brown	0.09	Dark	0.22
Dark	0.49	Blue	0.11	Dark Blue	0.31
Dark	0.54	Blue	0.15	Dark Blue	0.39
Dark	0.62	Light Pink	0.20	Blue	0.47
		Sky Blue	0.22	Light Violet	0.56
		Light Brown	0.24	Pale Yellow	0.71
		Light Blue	0.27	Violet	0.77
		Light Blue	0.30	Light Blue	0.87
		Sky Blue	0.38	Dark Blue	0.99
		Sky Blue	0.48		
		Blue	0.52		
		Brown	0.55		
		Light Green	0.58		
		Dark Blue	0.63		
		Red	0.67		
		Red	0.73		

HPTLC Chromatogram @ 254 nm:

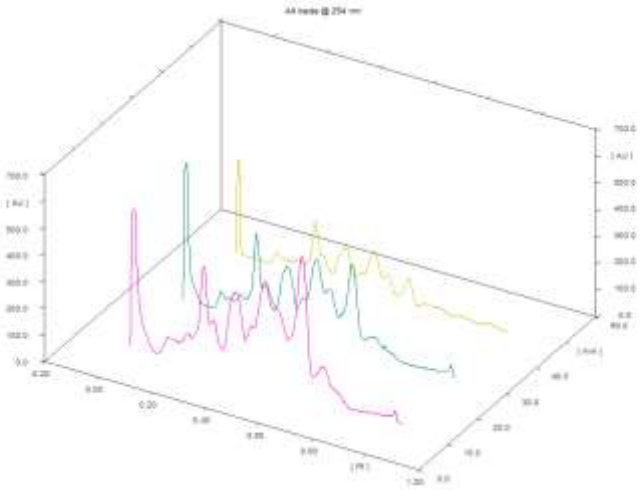


Peak Table @ 254 nm:

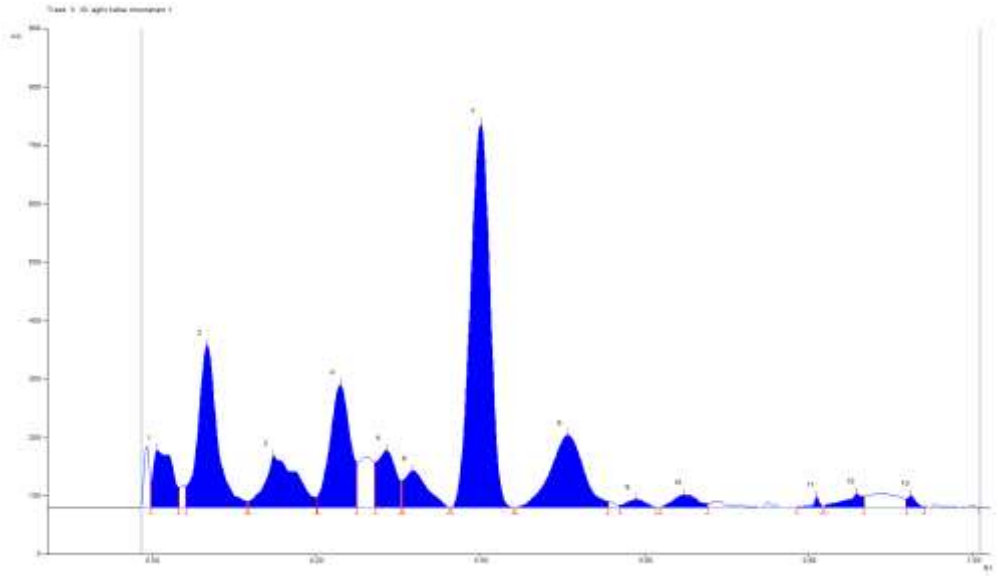
Track 3, ID: aghil kahai chooranam 1

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	-0.01 Rf	325.0 AU	-0.00 Rf	354.2 AU	26.55 %	0.01 Rf	0.3 AU	2447.8 AU	7.57 %
2	0.11 Rf	0.7 AU	0.14 Rf	44.8 AU	3.36 %	0.16 Rf	31.7 AU	1021.7 AU	3.16 %
3	0.20 Rf	31.0 AU	0.22 Rf	44.4 AU	3.33 %	0.24 Rf	35.3 AU	1351.7 AU	4.18 %
4	0.24 Rf	35.5 AU	0.28 Rf	208.3 AU	15.62 %	0.31 Rf	84.3 AU	5520.3 AU	17.06 %
5	0.31 Rf	84.6 AU	0.31 Rf	86.9 AU	6.52 %	0.35 Rf	31.1 AU	1941.9 AU	6.00 %
6	0.35 Rf	31.4 AU	0.40 Rf	140.8 AU	10.55 %	0.43 Rf	40.7 AU	5987.9 AU	18.51 %
7	0.43 Rf	40.9 AU	0.45 Rf	62.0 AU	4.65 %	0.46 Rf	60.3 AU	1258.8 AU	3.89 %
8	0.47 Rf	59.5 AU	0.50 Rf	158.0 AU	11.84 %	0.54 Rf	65.9 AU	6354.3 AU	19.64 %
9	0.54 Rf	66.0 AU	0.56 Rf	84.8 AU	6.36 %	0.59 Rf	19.9 AU	2247.1 AU	6.95 %
10	0.59 Rf	19.9 AU	0.64 Rf	92.2 AU	6.91 %	0.67 Rf	0.1 AU	2819.8 AU	8.72 %
11	0.67 Rf	0.2 AU	0.69 Rf	15.6 AU	1.17 %	0.70 Rf	14.9 AU	233.4 AU	0.72 %
12	0.73 Rf	12.7 AU	0.75 Rf	17.7 AU	1.33 %	0.79 Rf	0.9 AU	530.5 AU	1.64 %
13	0.81 Rf	3.6 AU	0.83 Rf	11.1 AU	0.83 %	0.86 Rf	4.4 AU	292.6 AU	0.90 %
14	0.91 Rf	1.5 AU	0.93 Rf	13.3 AU	0.99 %	0.97 Rf	0.9 AU	341.2 AU	1.05 %

3D Chromatogram @ 254 nm:



HPTLC Chromatogram @ 366 nm:

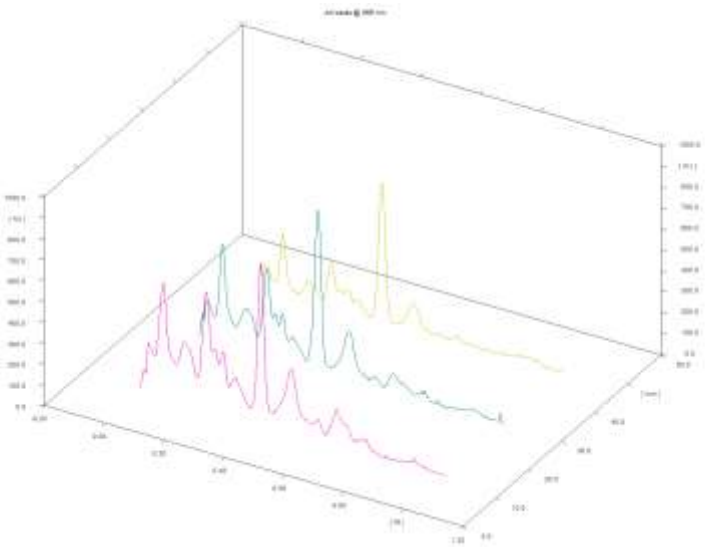


Peak Table @ 366 nm:

Track 3, ID: aghil kahai chooranam 1

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	-0.00 Rf	42.9 AU	0.01 Rf	98.9 AU	5.78 %	0.03 Rf	34.3 AU	2070.4 AU	5.27 %
2	0.04 Rf	35.9 AU	0.07 Rf	278.1 AU	16.25 %	0.12 Rf	10.6 AU	5824.6 AU	14.83 %
3	0.12 Rf	10.9 AU	0.15 Rf	88.1 AU	5.15 %	0.20 Rf	16.9 AU	3065.8 AU	7.80 %
4	0.20 Rf	17.9 AU	0.23 Rf	210.0 AU	12.27 %	0.25 Rf	77.0 AU	4646.3 AU	11.83 %
5	0.27 Rf	77.0 AU	0.29 Rf	97.5 AU	5.70 %	0.30 Rf	44.9 AU	2030.0 AU	5.17 %
6	0.31 Rf	45.0 AU	0.32 Rf	62.7 AU	3.66 %	0.36 Rf	0.1 AU	1575.6 AU	4.01 %
7	0.37 Rf	0.1 AU	0.40 Rf	656.6 AU	38.36 %	0.44 Rf	0.4 AU	13955.4 AU	35.53 %
8	0.44 Rf	0.0 AU	0.51 Rf	123.6 AU	7.22 %	0.56 Rf	9.3 AU	4486.4 AU	11.42 %
9	0.57 Rf	3.4 AU	0.59 Rf	13.5 AU	0.79 %	0.62 Rf	0.2 AU	279.7 AU	0.71 %
10	0.62 Rf	0.1 AU	0.65 Rf	21.1 AU	1.23 %	0.68 Rf	6.4 AU	568.3 AU	1.45 %
11	0.79 Rf	0.3 AU	0.81 Rf	17.9 AU	1.04 %	0.82 Rf	3.5 AU	115.6 AU	0.29 %
12	0.82 Rf	4.4 AU	0.86 Rf	23.5 AU	1.37 %	0.87 Rf	19.7 AU	467.7 AU	1.19 %
13	0.92 Rf	14.5 AU	0.93 Rf	20.0 AU	1.17 %	0.94 Rf	1.1 AU	197.2 AU	0.50 %

3D Chromatogram @ 366 nm:



BIO-CHEMICAL ANALYSIS OF TRIAL MEDICINE

Preparation of Sodium Carbonate extract:

2 gm of the sample drug is mixed 5 gm of Sodium carbonate and taken in a 100 ml beaker and 20 ml of distilled water is added. The solution is boiled for 10 minutes, cooled and then filtered. The filtrate is called sodium carbonate extract.

S.No	EXPERIMENT	OBSERVATION	INFERENCE
I	**TEST FOR ACID RADICALS**		
1a	**Test for Sulphate** 2 ml of the above prepared extract is taken in a test tube. To this add 2ml of 4% Ammonium oxalate solution.	Absence of White Precipitate	Absent
b	2ml of extract is added with 2ml of dilute hydrochloric acid until The effervescence ceases off. Then 2ml barium chloride solution is added.	Absence of White Precipitate	Absent
2	**Test for Chloride:** 2ml of extract is added with dilute nitric acid till the effervescence ceases. Then 2ml of silver nitrate solution is added.	white precipitate obtained	Absent
3	**Test for Phosphate** 2ml of the extract is treated with 2 ml of Ammonium molybdate solution and 2ml of concentrated nitric acid.	Yellow precipitate Obtained	Absent
4	**Test for Carbonate:** 2ml of the extract is treated with 2ml of magnesium sulphate solution.	Absence of white Precipitate	Absent
5	**Test for Sulphide:** 1 gm of the substance is treated with 2ml of concentrated Hcl.	Absence of Rotten egg smelling	Absent
6	**Test for Nitrate:** 1gm of the substance is heated with copper turnings and	Absence of reddish Brown gas.	Absent

	concentrated sulphuric acid and viewed the test tube vertically down.		
7a	**Test for Fluoride and oxalate** 2ml of the extract is added with 2ml of dilute acetic acid and 2ml of calcium chloride solution and heated.	Absence of white Precipitate	Absent
b	5 drops of clear solution is added with 2ml of diluted sulphuric acid and slightly warmed to this, 1 ml of dilute potassium permanganate Solution is added.	KMNO4 solution Discolourisation obtained	Absent
8	**Test for Nitrite** 3 drops of the extract is placed on a filter paper. On that, 2 drops of Acetic Acid and 2 drops of Benzidine solution is placed.	Absence of yellowish red colour	Absent
9	**Test for Borate** 2 pinches of the substance is made into paste by using Sulphuric acid and Alcohol (95%) and introduced into the blue flame.	Absence of Green tinged flame	Absent
II	**TEST FOR BASIC RADICALS**		
10	**Test for lead** 2 ml of the extract is added with 2 ml of Potassium iodide solution.	Absence of Yellow Precipitate	Absent
11a	**Test for Copper** One pinch of substance is made into paste with concentrated Hydrochloric acid in a watch glass and introduced into the non-luminous part of the flame.	Absence of Bluish green coloured Flame.	Absent
b	2ml of the extract is added with excess of Ammonia solution	Absence of deep Blue	Absent
12	**Test for Aluminium** To the 2 ml of extract. Sodium Hydroxide solution is added in drops to excess	Absence of White Precipitate.	Absent

13a	**Test for Iron** To the 2 ml of extract, 2 ml of Ammonium Thiocyanate Solution is added.	Absence of Blood red colour	Present
b	To the 2 ml of extract, 2 ml of Ammonium Thiocyanate solution and 2 ml of concentrated Nitric Acid is added.	Blood red colour obtained	Present
14	**Test for Zinc** To the 2 ml of extract Sodium Hydroxide solution is added in drops to excess.	Absence of White Precipitate.	Absent
15	**Test for Calcium** 2 ml of the extract is added with 2 ml of 4% Ammonium Oxalate solution.	Absence of White Precipitate.	Present
16	**Test for Magnesium** 2ml of extract, Sodium Hydroxide solution is added in drops to excess.	Absence of White Precipitate.	Absent
17	**Test for Ammonium** 2 ml of extract few ml of Nessler's Reagent and excess of Sodium Hydroxide solution are added.	Absence of Reddish brown precipitate	Absent
18	**Test for Potassium** A pinch of substance is treated with 2 ml of Sodium Nitrite solution and then treated with 2 ml of Cobal Nitrate in 30% glacial Acetic acid.	Absence of Yellow precipitate	Absent
19	**Test for Sodium** 2 pinches of the substance is made into paste by using Hydrochloric acid and introduced into the blue flame.	Absence of Yellow colour flame	Absent
20	**Test for Mercury** 2 ml of the extract is treated with 2 ml of Sodium Hydroxide solution.	Absence of yellow precipitate	Absent

21	**Test for Arsenic** 2 ml of extract is treated with 2 ml of silver Nitrate solution.	Absence of Yellow precipitate	Absent
22	**Test for Starch** 2ml of extract is treated with weak iodine solution	Absence of Blue colour	Absent
23	**Test of reducing Sugar** 5ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 10 drops of the extract and again boiled for 2 minutes. The colour changes are noted.	Absence of Green colour	Present
24	**Test of the alkaloids** 2ml of the extract is treated with 2ml of potassium lodide solution.	Absence of Red colour	Absent
25	**Test of the proteins** 2ml of the extract is treated with 2ml of 5% NaOH, mix well and add 2 drops of copper sulphate solution.	Absence of Violet colour	Absent

RESULTS:

The given sample (Aghil kattai Chooranam) contains

Calcium

Iron

Reducing sugar.

GOVERNMENT SIDDHA MEDICAL COLLEGE
Arumbakkam, Chennai-106

Communication Of The Decision Of Institutional Ethics Committee (IEC)

IEC No: GSMC-CH-ME-4/2015/004

Protocol title:

A CLINICAL STUDYON VELLAI NOI (LEUCORRHOEA) WITH THE EVALUATION OF SIDDHA DRUG AGIL KATTAI CHOORANAM

Principal Investigator: DR.X. HELEN SATHIYA

Name & Address of Institution :

Government siddha medical college,

Arumbakkam, Chennai-106

[✓] New Review [ ] Revised Review [ ] Expedited Review

Date of review (DD/MM/YY): 26-03-2015

Date Of Previous Review, If Revised Application :

Decision of the IEC

[✓] Recommended [ ] Recommended with suggestions

[ ] Revision [ ] Rejected

Suggestions / Reasons / Remarks :
1. In Investigation, add VDRL and HIV
2 Instead of USGi-Abdomen, add USGi - pelvis

Recommended for a period of 1 year
from date of completion of preclinical studies:

Please Note:

- Inform IEC immediately in case of any adverse events/serious drug reaction.
- Seek IECapproval in case of any change in the study procedure, site and investigator
- This approval is valid only for period mentioned above
- IEC member have the right to review the trial with prior intimation.

26/3/15

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.V. Banumathi
Member Secretary

INSTITUTIONAL ETHICS COMMITTEE

Date:

Sub: IEC review of research proposals.

Ref:Your letter dated

MEMBERS	PARTICIPATION	SIGNATURE
DR.P.JEYAPRAKASH NARAYANAN M.D(S)., Chairman	✓	
DR.V.BANUMATHI M.D(S)., Member Secretary		
DR.N.KABILAN M.D(S)., Clinician- Siddha	✓	26/3/15
DR.P.SATHIYA RAJESWARAN M.D(S)., Clinician- Siddha	✓	26/3/15
DR.G.AADINAAATH REDDY,M.Pharm, Ph.D., Pharmacologist	✓	Aadinaath 26/03/2015
DR.S.THILAGAVATHY Msc.,Ph.D., Social Scientist	✓	26/3/15
DR.T.MAHALAKSHMI M.A.,Ph.D., Linguistic Expert	✓	T. Mahalakshmi 26.3.15
DR.P.VIDYA M.B.B.S., DMRD., Modern Medicine Expert	✓	26/3/15
MR.P.SARAVANAN., Puplic Person	✓	

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.V.Banumathi
Member Secretary

BIOSTATISTICAL ANALYSIS

CLINICAL PROGNOSIS

Treatment for Vellainoi:

The most popular non parametric statistical tool, namely, McNemar Test analysis has been employed to analyses the effectiveness with the help of a hypothesis.

S. No	Signs&Symptoms	Before Treatment	After Treatment
		n%	n%
1.	Whitish (Curdy like)/ Yellowish discharge	20(100)	7(35)**
2.	Foul smelling discharge	14(70)	0(0)**
3.	Pruritis vulva	20(100)	3(15)**
4.	Dysuria	15(75)	0(0)**
5.	Low backache and lower abdominal pain	20(100)	3(15)**
6.	Infection due to *candida albicans* (As per evidence)	6(30)	6(30)
7.	Infection due to *Gardnerellavaginalis* (As per evidence)	14(70)	0(0)**
8.	Constipation	16(80)	0(0)**

McNemat test, C.I: 95%, *P<0.05; **P<0.01

Software: spss17 version

Number of cases: 20

Inference:

Since the p value is significant in all signs and symptoms except infection due to *Candida albicans*. So there is significant reducing of signs & symptoms except infection due to *Candida albicans* among the patients for the treatment of *Vellainoi.* Hence it is concluded that the treatment was effective and **significant.**

அரசு சித்த மருத்துவக் கல்லூரி, சென்னை-106

அறிஞர் அண்ணா மருத்துவமனை, சென்னை

வெள்ளை நோய்க்கான சித்த மருந்தின் (அகில் கட்டை சூரணம்)

பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

ஒப்புதல் படிவம்

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் இந்த ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர் :

நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும், தொடர்ந்து எனது உடல் இயக்கத்தை கண்காணிக்கவும், அதனை பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது, காரணம் எதுவும் கூறாமல், எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்து கொள்ளும் உரிமையை தெரிந்திருக்கின்றேன். நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு வெள்ளை நோய்க்கான அகில் கட்டை சூரணம் மருந்தின் பரிகரிப்பு திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர் :

தேதி: சாட்சிக்காரர் கையொப்பம்:

இடம்: பெயர் :

உறவுமுறை :

துறைத்தலைவர் கையொப்பம்: **ஆராய்ச்சியாளர் கையொப்பம்:**

INFORMED CONSENT FORM

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant:

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely."

Date:

Signature of a witness Left thumb Impression of the Participant

(Selected by the participant bearing no connection with the survey team)

Date:

Station:

Signature of participant:

Signature of the Guide: Signature of the Investigator:

CASE SHEET PROFORMA FOR *VELLAI NOI*

(LEUCORRHOEA)

GOVT. SIDDHA MEDICAL COLLEGE & HOSPITAL, CHENNAI-106

POST GRADUATE DEPARTMENT BRANCH –I MARUTHUVAM

Duration: 2015-2017

Op No / Ip No	:	Occupation	:
Ward No	:	Income /Month	:
Bed No	:	Nationality	: Indian
Name	:	Religion	:
Age	:	D.O.A	:
Sex	:	D.O.D	:
Permanent Address	:	No of Days Treated	:
		Diagnosis	:
		Result	:

Temporary Address : Govt. Siddha Medical College
Chennai - 606106

1. Complaints and duration :

2. History of present illness :

3. History of past illness :

4. Personal history :

Marital History :

Occupation :

Environment :

Social History :

Habits :

5. Menstrual history :

1. Age at menarche_____ year

2. Regularly of cycle Regular Irregular

3. Length of cycle (Days)

4. Duration of flow (Days)

5. Dysmenorrhoea started at age _____ years

6. Presence of abdominal pain other than around the time of menstruation

1. Yes 2.No

VAGINAL DISCHARGE

1. Colour - a. Yellow b. Green c. White d. Blood stained

2. Consistency - a. Thin b. Thick c. Creamy

3. Amount - a. Mild b. Moderate c. Profuse

4. Odour: 1.Yes 2. No

6. Family History :

SIDDHA ASPECT

NILAM

Kurinchi :

Mullai :

Marutham :

Neithal :

Palai :

PARUVA KALAM

Kaar : (Aavani, Purattasi)

Koothir : (Ayppasi, Karthigai)

Munpani : (Maarkazhi, Thai)

Pinpani : (Maasi, Panguni)

Elavenil : (Chittirai,Vaikasi)

Muduvenil : (Aani,Aadi)

YAAKKAI (Udal)

Vaatham :

Pittham :

Kabam :

Kalappu :

GUNAM

Satthuvam :

Rajotham :

Thamasam :

PORI/PULANGAL (SENSORY ORGANS)

Mei –Sensation :

Vaai – Taste :

Kan – Vision :

Mooku - Smell :

Sevi – Hearing :

KANMENTHRIYAM/KANNMA VIDAYAM [MOTOR ORGANS]

Kai- Dhaanam :

Kaal-Kamanam :

Vaai-Vasanam :

Eruvaai- Visarkkam :

Karuvaai-Aanantham :

UYIR THATHUKKAL

VATHAM

Piranan :

Abanan :

Viyanan :

Udanan :

Samanan :

Nagan :

Koorman :

Kirukaran :

Devathathan :

Thananjeyan :

PITHAM

Anarpitham :

Ranjagapitham :

Saathagapitham :

Pirrasagapitham :

Alosagapitham :

KAPAM

Avalambagam :

Kilethagam :

Pothagam :

Tharpagam :

Santhigam :

UDALTHAATHUKKAL

Saaram :

Senner :

Oon :

Kozhuppu :

Enbu :

Moolai :

Sukkilam/Suronitham :

ENVAGAI THERVUGAL

1. Naa :
2. Niram :
3. Mozhi :
4. Vizhi :
5. Malam :
6. Moothiram
    a) NeerKuri :
    b) NeiKuri :
7. Sparisam :
8. Naadi :

MALAM

Niram :

Edai :

Erugal :

Elagal :

MOOTHIRAM

1. Neerkuri

    Niram :

    Manam :

    Edai :

    Nurai :

    Enjal :

2. Neikuri

MODERN METHODS:

GENERAL EXAMINATION

Consciousness and Intelligence :

Voice and Speech :

General appearance :

Height and Weight :

Anaemia :

Jaundice :

Cyanosis :

Clubbing :

JVP :

Tracheal deviation :

Pedal oedema :

Lymphadenopathy :

Vital Signs

Body Temp :

Pulse :

Respiratory rate :

Blood Pressure :

INVESTIGATION

A) BLOOD INVESTIGATIONS:

BLOOD INVESTIGATIONS		BEFORE TREATMENT	AFTER TREATMENT
Hb (gms/dl)			
T. RBC(millions cells/cu.mm)			
ESR(mm)	½ hr		
	1 hr		
T.WBC (cells/cu.mm)			
Differential Count (%)	Polymorphs		
	Lymphocytes		
	Monocytes		
	Eosinophils		
	Basophils		

BLOOD INVESTIGATIONS		BEFORE TREATMENT	AFTER TREATMENT
Blood glucose (mg/dl)	F		
	PP		
Renal Function Test	Blood Urea		
	Serum Creatinine		

B) URINE INVESTGATIONS:

URINE INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
Albumin		
Sugar		
Deposits		
Urine Culture & Sensitivity		

C) SPECIFIC INVESTICATIONS:

PAP SMEAR/ WET SMEAR

Before	
After	

D) USG – Abdomen

CLINICAL SIGN AND SYMPTOMS OF VELLAI NOI

S. NO	CLINICAL FEATURES	BEFORE TREATMENT	DURATION TREATMENT						AFTER TREATMENT
			14TH Day	21TH Day	28TH Day	35TH Day	42TH Day	49TH Day	
1	Colour								
2	Consistency								
3	Amount								
4	Odour								
5	Low backache								
6	Abdominal pain								
7	Vagina becomes tender with irritation								
8	Burning and often dysuria								

Others specify, if any:

DIAGNOSIS

VELLAI NOI (LEUCORRHOEA)

TRIAL DRUG : **AGHIL KATTAI CHOORANAM**

DOSE : 1 Gram, Twice a day

ANUBANAM : Butter

DURATION OF TREATMENT: 48 Days

DATE	DAILY REPORT	MEDICINE

Medical Officer Signature: **HOD**

BIBLIOGRAPHY

1. A. Ramalingam, G. Veluchamy. Heritagge of Tamil Siddha Medicine, International Institute of Tamil Studies, First Edition, Pg no - 46.
2. C.K. Sambath, Antiquity of Siddha system, Directorate of Indian Medicine and Homeopathy, 1998, Pg.no-49.
3. Dr.P.Jayaprakash Narayanan et.al, Siddha medicine, Vol – II, Fundamentals,Tamil Valarchi Kazhagam, 2011, Pg. no – 16.
4. K. Anbarasu B.s.m.s, Yougi Vaithiya Chinthaamani, Thaamarai Noolagam, Chennai – 26, 2013, Pg.no – 423.
5. Parashari A, Singh V, Sodhanni P et.al, Clinical & etiological profile of reproductive tract infections among women attending gynaecological OPD at major city hospital.
6. K. Anbarasu B.s.m.s, Yougi Vaithiya Chinthaamani, Thaamarai Noolagam, Chennai – 26, 2013, Pg.no -163.
7. Howkins & Bourne et.al, Shaw's Textbook of Gynaecology, Elsevier, a division of Reed Elsevier India Private Limited, 2011, Pg.no-133.
8. Ananthanarayan & Paniker's, Text book of Microbiology, Universities Press (India) Private Limited 2009, 2010, Pg no- 401, 607.
9. Dr. N. Kuppusamy Mudhaliyar, H.B.I.M, Siddha Maruthuvam, Indian Medicine and Homeopathy, Chennai – 106, 2012, Pg no – 480.
10. Dr. C. Ramakrishnan, Maathar Noyum Maruthuvamum, Century book house private limited, 1992, Pg. no- 57.
11. K. Anbarasu B.s.m.s, Yougi Vaithiya Chinthaamani, Thaamarai Noolagam, Chennai – 26, 2013, Pg.no-164.
12. R.C.Mohan, Agathiyar Gunavaagadam, Thamarai Noolagam, Pg.no-269.
13. R.C.Mohan, Thirumoolar karukkadai vaithiyam, Thaamarai Noolagam, 2012, Pg. no- 18.
14. S.P.Ramachandran, Agathiyar Vaithiya Kaaviyam 1500, Thamarai Noolagam, Oct 2014, Pg. no – 6.
15. T.V. Sambasivam Pillai, Tamil – English dictionary, Volume 2, Directorate of Indian Medicine and Homeopathy, Second Edition 1991, Pg. no.-1589.
16. Dr.P.M.Venugopal, Mahalir Maruthuvam, Directorate of Indian Medicine and Homeopathy, 2008, Pg.no – 54.

17. Dr. N. Kuppusamy Mudhaliyar, H.B.I.M, Siddha Maruthuvam, Indian Medicine- Homeopathy, Chennai – 106, 2012, Pg.no – 480.
18. K. Anbarasu B.s.m.s, Yougi Vaithiya Chinthaamani, Thaamarai noolagam, Chennai – 26, 2013, Pg. no – 423.
19. Dr. N. Kuppusamy Mudhaliyar, H.B.I.M, Siddha Maruthuvam, Indian Medicine- Homeopathy, Pg. no – 480
20. T.R.Mahadeva Pandithar, Roga Nirnaya Saaram, Thamarai Noolagam, 1995, Pg.no. 88
21. Dr.P.M.Venugopal, Mahalir Maruthuvam, Directorate of Indian Medicine and Homeopathy, 2008, Pg. no-114,124
22. Dr. N. Kuppusamy Mudhaliyar, H.B.I.M, Siddha Maruthuvam, Indian Medicine- Homeopathy, Pg.no-485,486
23. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-363.
24. Dr. N. Kuppusamy Mudhaliyar, H.B.I.M, Siddha Maruthuvam, Indian Medicine- Homeopathy, Pg.no-491.
25. Dr. S. Venkatarajan L.I.M, Therayar Piniyari Muraimai, Part- II, Saraswathy Mahal Noolagam, Thanjavur, Third Edition 2006, Pg.no.106
26. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-270.
27. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-36,140.
28. R.C.Mohan, Agathiyar Gunavaagadam, Thamarai Noolagam, 137.
29. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-137,327.
30. S.B,Ramachandran, Therayar Neerkuri-Neikuri nool, Thamarai Noolagam, 2000, Pg.no-3.
31. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-299.
32. Dr. K. Thurairasan, H.P.I.M., Siddha Hygiene and Preventive Medicine, Directorate of Indian Medicine and Homeopathy, 1993, Pg.no-2.
33. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-243.

34. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-27.
35. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-259.
36. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-23.
37. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-24.
38. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-25.
39. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-30.
40. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-139.
41. Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006, Pg.no-232.
42. R.C.Mohan, Pathartha guna Chinthamani, Thamarai Noolagam, 2012, Pg.no-304.
43. Howkins & Bourne et.al, Shaw's Textbook of Gynaecology, Elsevier, a division of Reed Elsevier India Private Limited, 2011, Pg.no-1,2,3.
44. K.Bhasker rao et.al, Clinical Gynecology, Orient Lonman, 4th edition, Pg.no-2.
45. A.S.Moni, Medical Anatomy, Mrs.U.Bagavathy, 2009, Vol-II, Pg.no-271.
46. Howkins & Bourne et.al, Shaw's Textbook of Gynaecology, Elsevier, a division of Reed Elsevier India Private Limited, 2011, Pg.no-129
47. Howkins & Bourne et.al, Shaw's Textbook of Gynaecology, Elsevier, a division of Reed Elsevier India Private Limited, 2011, Pg.no-5.
48. Howkins & Bourne et.al, Shaw's Textbook of Gynaecology, Elsevier, a division of Reed Elsevier India Private Limited, 2011, Pg.no-129.
49. A.S.Moni, Medical Anatomy, Mrs.U.Bagavathy, 2009, Vol-II, Pg.no-271.
50. A.S.Moni, Medical Anatomy, Mrs.U.Bagavathy, 2009, Vol-II, Pg.no-258.
51. A.S.Moni, Medical Anatomy, Mrs.U.Bagavathy, 2009, Vol-II, Pg.no-266.
52. K.Bhasker rao et.al, Clinical Gynecology, Orient Lonman, 4th edition, Pg.no-4.
53. Indebir Singh et.al, Text book of Anatomy with colour atlas, Jaypee Brothers Medical Publishers (P) Ltd, Second edition, Vol-II, Pg.no-707.

54. A.S.Moni, Medical Anatomy, Mrs.U.Bagavathy, 2009, Vol-II, Pg.no-253.
55. K.Bhasker rao et.al, Clinical Gynecology, Orient Lonman, 4th edition, Pg.no-101.
56. Stuvart et.al, Indian Journal of Basic and applied Medical research, March 2016, Vol-5, Issue-2, p.601-605.
57. K.Bhasker rao et.al, Clinical Gynecology, Orient Lonman, 4th edition, Pg.no-101.
58. Howkins & Bourne et.al, Shaw's Textbook of Gynaecology, Elsevier, a division of Reed Elsevier India Private Limited, 2011, Pg.no-130.
59. Howkins & Bourne et.al, Shaw's Textbook of Gynaecology, Elsevier, a division of Reed Elsevier India Private Limited, 2011, Pg.no-131.
60. Howkins & Bourne et.al, Shaw's Textbook of Gynaecology, Elsevier, a division of Reed Elsevier India Private Limited, 2011, Pg.no-146.
61. Virendra N. Sehgal et.al, Venereal Diseases, Jaypee Brothers Medical Publishers (P) Ltd, 3rd edition, Pg.no-173.
62. Howkins & Bourne et.al, Shaw's Textbook of Gynaecology, Elsevier, a division of Reed Elsevier India Private Limited, 2011, Pg.no-146.
63. Howkins & Bourne et.al, Shaw's Textbook of Gynaecology, Elsevier, a division of Reed Elsevier India Private Limited, 2011, Pg.no-131.
64. Bailey & Scoott's et.al, Diagnostic Microbiology, 12th edition, Pg.no-866,867.
65. Howkins & Bourne et.al, Shaw's Textbook of Gynaecology, Elsevier, a division of Reed Elsevier India Private Limited, 2011, Pg.no-131.
66. K.Bhasker rao et.al, Clinical Gynecology, Orient Lonman, 4th edition, Pg.no-101,102,103.
67. Bailey & Scoott's et.al, Diagnostic Microbiology, 12th edition, Pg.no-868.
68. R.C.Mohan, Agasthiyar paripooranam 400, Thamarai noolagam, 2012, Pg.no-111.
69. K.S. Murugesa Muthaliyar, Gunapadam-Mooligai vaguppu, Directorate of Indian Medicine and Homeopathy, 2006, Pg.no-426.
70. Habibur Rahman, Scholars.J.App.Med.Sci 2013; 1(1):13-15 ISSN 2320-6691.
71. Harish Nayake et.al, International Journal of Recent Scientific Research.ISSN:0976-3031VOL.5, ISSUE, 2, PP.518-521, February, 2014.
72. K.S. Murugesa Muthaliyar, Gunapadam-Mooligai Vaguppu, Directorate of Indian Medicine and Homeopathy, 2006, Pg.no-113.

73. K.S. Murugesa Muthaliyar, Gunapadam-Mooligai Vaguppu, Directorate of Indian Medicine and Homeopathy, 2006, Pg.no-111.
74. K.S. Murugesa Muthaliyar, Gunapadam-Mooligai Vaguppu, Directorate of Indian Medicine and Homeopathy, 2006, Pg.no-467.
75. K.S. Murugesa Muthaliyar, Gunapadam-Mooligai Vaguppu, Directorate of Indian Medicine and Homeopathy, 2006, Pg.no-13.
76. K.S. Murugesa Muthaliyar, Gunapadam-Mooligai Vaguppu, Directorate of Indian Medicine and Homeopathy, 2006, Pg.no-311.
77. K.S. Murugesa Muthaliyar, Gunapadam-Mooligai Vaguppu, Directorate of Indian Medicine and Homeopathy, 2006, Pg.no-836.
78. Srikanth kagithoju et.al. Int.J.Pharm.Bio.Sci 2012 oct; 3(4) :(B) 291-303 ISSN 0975-6299.
79. K.S. Murugesa Muthaliyar, Gunapadam-Mooligai Vaguppu, Directorate of Indian Medicine and Homeopathy, 2006, Pg.no-54.
80. I.C Mohanty ET. Al, Journal of Medicinal Plant Research.VOL.8 (18).PP.669-685.10 MAY, 2014 Article no: 3F7257D44609, ISSN 1996-0875.
81. OECD Guideline for testing of Chemicals (2001) Guideline 423: Acute Oral Toxicity-Acute Toxic Class Method.
82. OECD Guide lines 407 for testing of chemicals. Repeated dose 28-Day Oral Toxicity Study in Rodents. 2008: pp 2- 8.
83. Jain N, Sharma P, Sharma N, Joshi S C. Haemato-biochemical profile following sub-acute toxicity of malathion in male albino rats. Pharmacologyonline. 2009; 2:500–506.
84. Suvarna, S.K., C.Layton and J.D. Bancroft. 2013. Bancroft's theory and practice of histological techniques. 7th edn, Churchill Livingstone, London